This amended and restated short form prospectus is a base shelf prospectus. This amended and restated short form prospectus has been filed under legislation in each of the provinces and territories of Canada that permits certain information about these securities to be determined after this amended and restated prospectus has become final and that permits the omission from this amended and restated prospectus of that information. The legislation requires the delivery to purchasers of a prospectus supplement containing the omitted information within a specified period of time after agreeing to purchase any of these securities, except in cases where an exemption from such delivery is available.

No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise. This amended and restated short form prospectus constitutes a public offering of these securities only in those jurisdictions where they may be lawfully offered for sale and only by persons permitted to sell these securities in those jurisdictions.

Information contained herein is subject to completion or amendment. A registration statement relating to these securities will be filed with the U.S. Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Information has been incorporated by reference in this amended and restated short form prospectus from documents filed with securities commissions or similar authorities in Canada. Copies of the documents incorporated herein by reference may be obtained on request without charge from the Chief Financial Officer of NervGen by email at badams@nervgen.com or at 112-970 Burrard Street, Unit 1290, Vancouver, British Columbia, V6Z 2R4, telephone 604 880 6056 or are available electronically at www.sedarplus.ca.

AMENDED AND RESTATED SHORT FORM BASE SHELF PROSPECTUS

(amending and restating the short form base shelf prospectus dated November 25, 2024)

New Issue and/or Secondary Offering ***December 15, 2025***

NERVGEN PHARMA CORP.

U.S.$150,000,000
Common Shares
Debt Securities
Subscription Receipts
Warrants
Units

This amended and restated prospectus relates to the offering for sale from time to time by NervGen Pharma Corp. (the "**Company**" or "**NervGen**") during the 25-month period that this prospectus, including any amendments hereto, remains effective, of up to U.S.$150,000,000 in the aggregate, in one or more series or issuances, of (i) common shares ("**Common Shares**") in our capital, (ii) our debt securities ("**Debt Securities**"), (iii) subscription receipts exercisable for equity securities and/or other securities ("**Subscription Receipts**"), (iv) warrants to purchase Common Shares or Debt Securities ("**Warrants**") and, (v) units comprised of one or more of the other securities described in this prospectus in any combination ("**Units**"). The securities may be offered by us or by our security holders. The securities may be offered separately or together, in amounts, at prices and on terms to be determined

based on market conditions at the time of the sale and set forth in an accompanying prospectus supplement. This prospectus may qualify an "at-the-market distribution", as defined in National Instrument 44-102 – *Shelf Distributions* (an "**ATM Distribution**").

The Company has applied to list the Common Shares on the Nasdaq Capital Market ("**Nasdaq**") under the symbol "NGEN". The ability to successfully list the Common Shares onto Nasdaq is uncertain. Our Common Shares are listed on the TSX Venture Exchange (the "**TSX-V**") under the symbol "NGEN" and the OTCQB® (the "**OTCQB**") under the symbol "NGEN-F". The closing price of the Common Shares on December 12, 2025, the last trading date before the date hereof, was $6.00 per Common Share on the TSX-V and U.S.$4.36 per Common Share on the OTCQB. Upon listing of the Common Shares on Nasdaq, the Common Shares will cease trading on the OTCQB. Unless otherwise specified in an applicable prospectus supplement, our Debt Securities, Subscription Receipts, Warrants and Units will not be listed on any securities or stock exchange or on any automated dealer quotation system.

There is currently no market through which our securities, other than Common Shares, may be sold and purchasers may not be able to resell such securities purchased under this prospectus. This may affect the pricing of our securities, other than Common Shares, in the secondary market, the transparency and availability of trading prices, the liquidity of these securities and the extent of issuer regulation. See "*Risk Factors*".

This offering is made by a Canadian issuer that is permitted, under a multijurisdictional disclosure system adopted by the United States and Canada, to prepare this prospectus in accordance with Canadian disclosure requirements. Prospective investors should be aware that such requirements are different from those of the United States. Financial statements included or incorporated herein, if any, have been prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board, and may be subject to foreign auditing and auditor independence standards, and thus may not be comparable to financial statements of United States companies.

Prospective investors should be aware that the acquisition of the securities described herein may have tax consequences both in the United States and in Canada. Such consequences for investors who are resident in, or citizens of, the United States or Canada may not be described fully herein. You should read the tax discussion in any applicable prospectus supplement with respect to any particular offering and consult your own tax advisor with respect to your own particular circumstances.

The enforcement by investors of civil liabilities under the United States federal securities laws may be affected adversely by the fact that the Company is incorporated or organized under the laws of British Columbia, Canada, that some or all of its officers and directors may be residents of Canada, that some or all of the underwriters or experts named in the registration statement may be residents of a foreign country, and that all or a substantial portion of the assets of the Company and said persons may be located outside the United States. See "*Enforceability of Civil Liabilities*".

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE U.S. SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION OR ANY U.S. REGULATORY AUTHORITY NOR HAVE THESE AUTHORITIES PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The specific terms of securities offered pursuant to this prospectus will be set forth in a prospectus supplement including, where applicable: (i) in the case of Common Shares, the number of Common Shares offered and the offering price; (ii) in the case of Debt Securities, the aggregate principal amount and offering price, the maturity date, the interest provisions, events of default, redemption or retraction provisions, conversion or exchange rights, whether the debt is senior or subordinated and any other specific terms; (iii) in the case of Subscription Receipts, the number of Subscription Receipts offered, the offering price, the securities issuable in exchange for the Subscription Receipts and any other specific terms; (iv) in the case of Warrants, the number of Common Shares issuable upon exercise thereof, the exercise price and exercise period and the terms of any provisions allowing or providing for adjustments in the exercise price or the number of Common Shares issuable upon exercise thereof; and (v) in the case of Units,

the number of Units offered, the offering price and the number of securities included in each Unit. A prospectus supplement may include specific variable terms pertaining to securities that are not within the alternatives and parameters set forth in this prospectus.

All information permitted under securities legislation to be omitted from this prospectus will be contained in one or more prospectus supplements that will be delivered to purchasers together with this prospectus, except in cases where an exemption from such delivery requirements has been obtained. Each prospectus supplement will be incorporated by reference into this prospectus for the purposes of securities legislation as of the date of the prospectus supplement and only for the purposes of the distribution of the securities to which the prospectus supplement pertains. You should read this prospectus and any applicable prospectus supplement carefully before you invest in any securities issued pursuant to this prospectus. This prospectus may not be used to sell any securities unless accompanied by a prospectus supplement. In connection with any underwritten offering of securities, the underwriters, dealers or placement agents may over-allot or effect transactions which stabilize or maintain the market price of the securities offered at a higher level than that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. A purchaser who acquires securities forming part of the underwriters' over-allocation position acquires those securities under this short form prospectus, regardless of whether the over-allocation position is ultimately filled through the exercise of the over-allotment option or secondary market purchases. See "*Plan of Distribution*". A prospectus supplement will set out the names of any underwriters, dealers or agents involved in the sale of our securities, the amounts, if any, to be purchased by underwriters, the plan of distribution for such securities, including the anticipated net proceeds to the Company from the sale of such securities, the amounts and prices at which such securities are sold and, if applicable, the compensation of such underwriters, dealers or agents.

We or any selling securityholder may offer and sell the securities issued under this prospectus to or through underwriters, dealers, placement agents or other intermediaries or directly to one or more purchasers, subject in each case to obtaining any required exemptions under applicable securities laws. The distribution of securities under this prospectus may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time, at market prices prevailing at the time of sale, or at prices related to such prevailing market prices, or at other negotiated prices, in each case as set forth in the applicable prospectus supplement. The prospectus supplement relating to a particular offering of securities will identify each selling securityholder, underwriter, dealer or agent engaged in connection with an offering and sale of securities pursuant to this prospectus and will set forth the terms of the offering of such securities, including our proceeds and, to the extent applicable, any fees, discounts, concessions or other compensation payable to the underwriters, dealers or agents, the method of distribution, the initial issue price (in the event that the offering is a fixed price distribution) and any other material terms of the plan of distribution. See "*Plan of Distribution*".

We are a clinical stage biopharmaceutical company dedicated to developing first-in-class neuroreparative therapeutics for spinal cord injury and other traumatic and neurologic disorders. Investing in our securities is speculative and involves a high degree of risk. An investment in our securities should only be undertaken by those persons who can afford the total loss of their investment. You should carefully read the "*Risk Factors*" in this prospectus (including any prospectus supplement) and in the documents incorporated by reference herein as well as the information under the heading "*Cautionary Note Regarding Forward-Looking Statements*". Potential investors are advised to consult their own legal counsel and other professional advisors in order to assess income tax, legal and other aspects of an investment in NervGen.

You should rely only on the information contained in or incorporated by reference into this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide investors with different information. Information contained on our website shall not be deemed to be a part of this prospectus (including any applicable prospectus supplement) or incorporated by reference and should not be relied upon by prospective investors for the purpose of determining whether to invest in the securities. We will not make an offer of these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the face page of this prospectus or any applicable prospectus supplement.

Our head office is located at 112-970 Burrard Street, Unit 1290, Vancouver, British Columbia, V6Z 2R4 and its registered and records offices are located at 1133 Melville Street, Suite 3500, The Stack, Vancouver BC V6E 4E5, Canada.

Purchasers are advised that it may not be possible for investors to enforce judgments obtained in Canada against any person or company that is incorporated, continued or otherwise organized under the laws of a foreign jurisdiction or resides outside of Canada, even if the party has appointed an agent for service of process. Dr. Randall E. Kaye, Krista McKerracher, Dr. Adam Rogers and Craig Thompson, directors of the Company, reside outside of Canada and have appointed NervGen as agent for service of process. See "*Agent for Service of Process*".

No underwriter has been involved in the preparation of this prospectus or performed any review of the contents of this prospectus.

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GENERAL MATTERS

About this Prospectus

You should rely only on the information contained or incorporated by reference in this prospectus or any applicable prospectus supplement and on the other information included in the registration statement of which this prospectus will form a part of and are not entitled to rely on only certain parts of the information contained in this prospectus, any applicable prospectus supplement or the registration statement of which this prospectus will form a part of to the exclusion of the remainder. We have not authorized anyone to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. We are not making an offer to sell or seeking an offer to buy the securities offered pursuant to this prospectus in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus or any applicable prospectus supplement is accurate only as of the date on the front of those documents and that information contained in any document incorporated by reference is accurate only as of the date of that document, regardless of the time of delivery of this prospectus or any applicable prospectus supplement or of any sale of our securities pursuant thereto. Our business, financial condition, results of operations and prospects may have changed since those dates.

Interpretation

In this prospectus and any applicable prospectus supplement, unless otherwise indicated or the context otherwise requires, the terms "NervGen", the "Company" and "we", "us" and "our" are used to refer to NervGen Pharma Corp.

This prospectus and any applicable prospectus supplement contain company names, product names, trade names, trademarks and service marks of other organizations, all of which are the property of their respective owners.

Market and Industry Data

This prospectus and any applicable prospectus supplement contain certain statistical, market and industry data obtained from government or other industry publications and reports, or based on estimates derived from same and management's knowledge of, and experience in, the markets in which the Company operates. Government and industry publications and reports generally indicate that information has been obtained from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. Further, certain of these organizations are participants in, or advisors to participants in, the pharmaceutical industry, and they may present information in a manner that is more favourable to the industry than would be presented by an independent source. Actual outcomes may vary materially from those forecast in such reports or publications, and the prospect for material variation can be expected to increase as the length of the forecast period increases. While the Company believes this data to be reliable, market and industry data is subject to variations and cannot be verified with complete certainty due to limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties inherent in any statistical survey. The Company has not independently verified any of the data from third party sources referred to in this prospectus and any applicable prospectus supplement or ascertained the underlying assumptions relied upon by such sources.

Currency

In this prospectus and any applicable prospectus supplement, unless otherwise indicated, all dollar amounts are expressed in Canadian dollars. References to "$" are to Canadian dollars and references to "U.S.$" and "U.S. dollars" are to United States dollars. See "*Financial and Exchange Rate Information*".

Cautionary Note for United States Investors

We are permitted under the multijurisdictional disclosure system adopted by the United States and Canada to prepare this prospectus, including the documents incorporated by reference herein and any prospectus supplement, in accordance with the requirements of Canadian securities law, which differ from the requirements of United States securities laws. Financial statements included or incorporated by reference herein have been prepared in accordance with IFRS Accounting Standards issued by the International Accounting Standards Board and thus may not be

comparable to the financial statements of United States companies. Our financial statements are subject to audit in accordance with Canadian generally accepted auditing standards, and our auditor is subject to Canadian auditor independence standards.

Cautionary Note Regarding Forward-Looking Statements

This prospectus, including the documents incorporated by reference herein, contains "forward-looking statements" within the meaning of U.S. securities laws and "forward-looking information" within the meaning of applicable Canadian securities legislation (collectively, the "forward-looking statements"). Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenue or performance, capital expenditures, financing and other information that is not historical information. These statements appear in a number of different places in this prospectus and can often be identified by words such as "anticipates", "estimates", "projects", "expects", "intends", "believes", "plans", "will", "could", "may", or their negatives or other comparable words. Such forward-looking statements are necessarily based on estimates and involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements.

Forward-looking statements in this prospectus, including the documentation incorporated by reference herein, include, but are not limited to, statements relating to our:

- expectations regarding the sufficiency of our capital resources and requirements for additional capital;
- requirements for, and the ability to obtain, future funding on favourable terms or at all, and the intended use of proceeds from financings;
- the successful listing of the Common Shares on the Nasdaq;
- business strategy;
- expected future loss and accumulated deficit levels;
- projected financial position and estimated cash expenditure rate;
- expectations about the timing of achieving milestones and the cost of our development programs;
- estimates of the size and characteristics of the potential markets for our product candidates;
- observations and expectations regarding the effectiveness and durability of drug candidates, NVG-291 and NVG-300, and the potential benefits to patients;
- ability to successfully develop NVG-291 and NVG-300;
- the term of NVG-291's and NVG-300's intellectual property protection;
- the impact of pandemics or any escalation thereof on our operations;
- plans to use and evaluate NVG-291 and other potential drug candidates in our clinical development programs;
- plans to develop additional proprietary compounds that address nervous system repair;
- expectations and intended benefits of memorandums of understanding and agreements entered into with third parties;

- expectations about the timing with respect to commencement and completion of clinical trials;
- expectations about the timing and future plans with respect to preclinical and clinical studies;
- expectations regarding the objectives, endpoints and evaluation criteria of our ongoing clinical trials;
- expectations relating to the removal of the partial clinical trial hold initiated by the U.S. Food and Drug Administration ("**FDA**");
- expectations regarding interactions with the FDA regarding future clinical development of our product candidates, including potential accelerated approval;
- expected results of toxicology studies with respect to NVG-291 and other potential drug candidates;
- expectations about our product candidates' safety and efficacy;
- ability to identify and secure sources of non-dilutive funding for the development of our product candidates and technologies;
- expectations regarding our ability to arrange for the manufacturing of our product candidates and technologies;
- expectations regarding the cost, progress and successful and timely completion of the various stages of the regulatory approval process;
- expectations about the potential benefits of Fast Track designation for NVG-291 in the treatment of spinal cord injury ("**SCI**");
- ability to secure strategic partnerships with larger pharmaceutical and biotechnology companies;
- strategy to acquire and develop new product candidates and technologies and to enhance the safety and efficacy of existing products and technologies;
- plans to market, sell and distribute our products and technologies, if approved;
- expectations regarding the acceptance of our products and technologies by the market, if approved;
- expectations regarding the use of our products and technologies in treating diseases and medical disorders;
- ability to retain and access appropriate staff, management, and expert advisers;
- expectations with respect to existing and future contractual obligations, corporate alliances and licensing transactions with third parties, and the receipt and timing of any payments to be made by the Company or to the Company in respect of such arrangements; and
- strategy and ability with respect to the protection of our intellectual property.

Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. In making the forward-looking statements included in this prospectus, we have made various material assumptions, including but not limited to:

- our ability to obtain financing on acceptable terms;
- additional sources of funding, including grants and funding from partners;
- our ability to attract and retain skilled staff;
- favourable general business and economic conditions;
- pandemics not having a material impact on our operations;
- our future research and development plans proceeding substantially as currently envisioned;
- our ability to obtain positive results from our research and development activities, including clinical trials;
- future expenditures to be incurred by us;
- research and development and operating costs;
- our ability to find partners in the pharmaceutical industry;
- the products and technology offered by our competitors;
- the impact of competition on our operations;
- our ability to identify additional product candidates;
- our ability to obtain regulatory and other approvals to commence additional clinical trials involving current and future product candidates;
- our ability to successfully out-license or sell our future products, if any, and in-license and develop new products;
- our ability to protect patents and proprietary rights; and
- expected research and development tax credits.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined herein under the heading "Risk Factors" and in the documents incorporated by reference herein and, if applicable, in any accompanying prospectus supplement filed relating to a specific offering or sale. Certain risks and uncertainties that could cause such actual events or results expressed or implied by such forward-looking statements and information to differ materially from any future events or results expressed or implied by such statements and information include, but are not limited to, the risks and uncertainties related to the fact that:

- we have a limited operating history, are early in our development efforts, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability;
- since our inception, we have incurred significant net losses and expect to continue to incur significant net losses for the foreseeable future and we may never achieve or maintain profitability;
- we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts;

- positive results from early preclinical studies and clinical trials of our current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our current or future product candidates. If we cannot replicate the positive results from our preclinical studies or early clinical trials of our current or future product candidates, we may be unable to successfully raise sufficient financing to develop, obtain regulatory approval for and commercialize our current or future product candidates;

- we have a history of negative operating cash flow and may continue to experience negative operating cash flow;

- raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;

- our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited;

- we are substantially dependent on the success of our lead product candidate, NVG-291, which is currently in a Phase 1b/2a clinical trial for SCI (CONNECT SCI Study). If we are unable to complete development of, obtain approval for and commercialize NVG-291 for SCI in a timely manner, our business will be harmed;

- there are currently no FDA-approved products for the treatment of SCI;

- the regulatory approval processes of the FDA, EMA, Health Canada and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to commercialize our product candidates and generate product revenue and our business will be substantially harmed;

- preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates;

- our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could delay or prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences. NVG-291 for SCI is currently subject to a partial clinical hold by the FDA, and we may be unable to have the hold removed which could adversely affect development of NVG-291 and our results of operations;

- the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, Health Canada or other comparable foreign regulatory authorities;

- interim, “topline,” and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data becomes available and are subject to audit and verification procedures that could result in material changes in the final data;

- if we fail to develop and commercialize NVG-291 for additional indications or fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired;

- we may expend our limited resources to pursue a particular product or indication and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success;

- changes in methods of product candidate manufacturing or formulation may result in additional costs or delay;

- if we are unable to successfully develop companion diagnostics or biomarkers that may be required for our therapeutic product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates;

- if we experience delays or difficulties in the enrollment and/or retention of participants in clinical trials, our clinical development activities could be delayed or otherwise adversely affected;

- as an organization, we have never conducted later-stage clinical trials or submitted a new drug application, and may be unable to do so for any of our product candidates;

- we face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted;

- Fast Track or Breakthrough Therapy designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates;

- we may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity;

- even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success;

- if the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer;

- if we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be successful in commercializing our product candidates that obtain regulatory approval;

- our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities of such materials on time or at an acceptable cost;

- we rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed;

- we may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans;

- if we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations;

- we may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets;

- even if our product candidates receive regulatory approval, they will be subject to significant post marketing regulatory requirements and oversight;

- obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions;

- any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations;

- we may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations;

- our relationships with healthcare professionals, clinical investigators, clinical research organizations ("**CROs**") and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings;

- failure to comply with laws, rules, regulations, policies, industry standards and contractual obligations relating to privacy, data protection and data security could adversely affect our business;

- if we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business;

- disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business;

- we are subject to certain U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations;

- if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business;

- our success depends on our ability to protect our intellectual property and our proprietary technologies;

- if the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected;

- intellectual property rights do not necessarily address all potential threats to our competitive advantage;

- patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time;

- others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects;

- if we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates;

- we may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad;

- we may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates;

- changes in U.S. patent law, or laws in other countries, or their interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates;

- we may not be able to protect or enforce our intellectual property rights throughout the world;

- if our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected;

- if we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position;

- our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of any future licenses granted to us by others;

- the patent protection and patent prosecution for some of our product candidates may be dependent on third parties;

- we depend heavily on our executive officers, principal consultants and others, and the loss of their services would materially harm our business;

- we only have a limited number of employees to manage and operate our business;

- our future growth may depend, in part, on our ability to operate internationally, where we would be subject to additional regulatory burdens and other risks and uncertainties;

- we expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations;

- the market price of our Common Shares may be volatile, and you could lose all or part of your investment;

- sales of a substantial number of shares of our Common Shares in the public market could cause our share price to fall;

- if we successfully list our Common Shares on the Nasdaq, we will be subject to the applicable provisions of the Sarbanes-Oxley Act of 2022, as amended. If we are unable to satisfy the requirements of the Sarbanes-Oxley Act of 2002, as amended, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned;

- our Common Shares do not currently trade on a stock exchange in the United States and we do not know whether a market for our Common Shares will develop to provide you with adequate liquidity;

- we do not intend to pay dividends on our Common Shares in the foreseeable future, so any returns will be limited to the value of our Common Shares;

- if securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Shares, the trading price or trading volume of our Common Shares could decline;

- we have broad discretion in the use of the net proceeds from any offering and may not use them effectively;

- investing in our securities is speculative, and investors could lose their entire investment;

- our constating documents permit us to issue an unlimited number of Common Shares without additional shareholder approval which could result in dilution;

- the exercise of stock options and warrants could cause dilution;

- it is possible that our status with regards to whether we are a "passive foreign investment company" may change, which could have adverse U.S. federal income tax consequences for U.S. shareholders;

- it may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence;

- upon effectiveness of a registration statement on Form F-10, we will become subject to the informational requirements of the Exchange Act; however, as a foreign private issuer, we will be subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to our U.S. shareholders;

- we have devoted, and will continue to devote significant resources to regulatory compliance as a public entity. These resource requirements will increase if we successfully list our Common Shares onto Nasdaq;

- there is currently no market through which our securities, other than our Common Shares, may be sold;

- the Debt Securities will be unsecured and will rank equally in right of payment with all of our future unsecured debt;

- our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition;

- cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, contract research organizations, CROs, third -party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations; and

- we may be subject to securities litigation, which is expensive and could divert management attention.

If one or more of these risks or uncertainties or a risk that is not currently known to us materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from those expressed or implied by forward-looking statements. The forward-looking statements represent our views as of the date of this prospectus. While we may elect to update these forward-looking statements in the future, we have no current intention to do so except as to the extent required by applicable securities law. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements. We advise you that these cautionary remarks expressly qualify in their entirety all forward-looking statements attributable to us or persons acting on our behalf.

Documents Incorporated by Reference

Information has been incorporated by reference in this prospectus from documents filed with securities commissions or similar authorities in each of the provinces and territories of Canada.

Copies of the documents incorporated by reference in this prospectus and not delivered with this prospectus may be obtained on request without charge from the Chief Financial Officer of NervGen by email at badams@nervgen.com or by accessing the disclosure documents through the Internet on SEDAR+, at www.sedarplus.ca or the Electronic Data Gathering, Analysis, and Retrieval System ("EDGAR") at www.sec.gov/edgar.

The following documents, filed with the securities commissions or similar regulatory authorities in each of the provinces and territories of Canada are specifically incorporated by reference, and form an integral part of, this prospectus:

- the annual information form dated April 29, 2025 for the year ended December 31, 2024 (the "**AIF**");
- the audited annual consolidated financial statements for the fiscal years ended December 31, 2024 and 2023, together with the notes thereto and the auditor's report thereon;
- the management's discussion and analysis of financial condition and results of our operations for the year ended December 31, 2024 (the "**Annual MD&A**");
- the unaudited condensed and consolidated interim financial statements for the three and nine months ended September 30, 2025, together with the notes thereto (the "**Interim Financial Statements**");
- the management's discussion and analysis of financial condition and results of our operations for the three and nine months ended September 30, 2025 (the "**Interim MD&A**");
- the management information circular dated April 2, 2025, distributed in connection with our annual general meeting of shareholders held on May 6, 2025;
- the material change report dated January 2, 2025 announcing the enrollment of the final subject in the chronic cohort of the Company's Phase 1b/2a proof-of-concept, double-blind, randomized placebo-controlled clinical trial (NCT05965700) evaluating NVG-291;
- the material change report dated April 4, 2025 announcing the Company's initiation of an expanded access policy to allow treatment use of the investigational product NVG-291 for those individuals with SCI;
- the material change report dated June 2, 2025 announcing positive topline data from the chronic cohort of the Company's Phase 1b/2a study of NVG-291;
- the material change report dated July 7, 2025 announcing the resignation of Daniel Mikol, the Company's Chief Medical Officer, the increased scope in the role of Randall Kaye, the Chief Medical Advisor, the resignation of Glenn Ives from the Board of Directors and the appointment of Dr. Adam Rogers as chair of the Board of Directors;
- the material change report dated July 25, 2025 announcing the departure of Mike Kelly, the Company's President and Chief Executive Officer, and the appointment of Dr. Adam Rogers as Interim CEO; and
- the material change report dated November 25, 2025 announcing the closing of a non-brokered private placement (the "**Private Placement**"), pursuant to which the Company issued 4,785,674 units at a price of U.S.$2.10 per unit for aggregate gross proceeds of U.S.$10,049,915.

Any documents of the type described in Section 11.1 of Form 44-101F1 – *Short Form Prospectus* filed with a securities commission or similar regulatory authority in Canada on or after the date of this prospectus and prior to the expiry of this prospectus, or the completion of the issuance of securities pursuant hereto, will be deemed to be incorporated by reference into this prospectus.

To the extent that any document or information incorporated by reference into this prospectus is filed with the U.S. Securities and Exchange Commission (the "**SEC**") pursuant to the United States *Securities Exchange Act* of 1934, as amended (the "**Exchange Act**") after the date of this prospectus, such document or information will be deemed to be incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part. In addition, if and to the extent expressly indicated therein, we may incorporate by reference in this prospectus documents that we file with or furnish to the SEC pursuant to Section 13(a), 13(c) or 15(d) of the *Exchange Act*.

Any template version of any "marketing materials" (as such term is defined in NI 44-101) filed by the Company after the date of a prospectus supplement and before the termination of the distribution of the securities offered pursuant to such prospectus supplement (together with this prospectus) is deemed to be incorporated by reference in such prospectus supplement.

A prospectus supplement containing the specific terms of any offering of our securities will be delivered to purchasers of our securities together with this prospectus and will be deemed to be incorporated by reference in this prospectus as of the date of the prospectus supplement and only for the purposes of the offering of our securities to which that prospectus supplement pertains.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document that also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes. The making of a modifying or superseding statement is not to be deemed an admission for any purposes that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of material fact or an omission to state a material fact that is required to be stated or is necessary to make a statement not misleading in light of the circumstances in which it was made. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

Upon our filing of an annual information form, any subsequent annual information forms or any new annual financial statements and the accompanying management's discussion and analysis, or upon the re-filing of any amended annual information forms, annual financial statements or the accompanying management's discussion and analysis, with applicable securities regulatory authorities during the currency of this prospectus, the previous, if applicable, annual information form, annual financial statements and management's discussion and analysis and all quarterly financial statements, material change reports and information circulars filed prior to the commencement of our financial year in which a new annual information form is filed will be deemed no longer to be incorporated into this prospectus for purposes of future offers and sales of our securities under this prospectus.

Upon interim consolidated financial statements and the accompanying management's discussion and analysis being filed by us with the applicable securities regulatory authorities during the duration of this prospectus, all interim consolidated financial statements and the accompanying management's discussion and analysis, filed prior to the new interim consolidated financial statements shall be deemed no longer to be incorporated into this prospectus for the purposes of future offers and sales under this prospectus.

References to our website in any documents that are incorporated by reference into this prospectus do not incorporate by reference the information on our website into this prospectus, and we disclaim any such incorporation by reference.

Financial and Exchange Rate Information

The annual consolidated financial statements of the Company incorporated by reference in this prospectus have been prepared in accordance with IFRS and are reported in Canadian dollars, and the audit of such financial statements may be subject to Canadian auditing and auditor independence standards.

The following tables set forth, for the periods indicated, certain exchange rates based on the Bank of Canada daily average exchange rate for one U.S. dollar, expressed in Canadian dollars.

	Year Ended December 31,			Nine Months Ended September 30,
	2022	**2023**	**2024**	**2025**
Lowest rate during the period.....	1.2451	1.3128	1.3316	1.3558
Highest rate during the period	1.3856	1.3875	1.4416	1.4603
Rate at the end of the period.....	1.3544	1.3226	1.4389	1.3921
Average rate for the period[(1)].....	1.3011	1.3497	1.3698	1.3988

Note:

(1) Determined by calculating the simple average of the daily average exchange rate for 2022, 2023, 2024 and the nine months ended September 30, 2025.

On December 12, 2025 the daily average exchange rate as quoted by the Bank of Canada was $1.00 = U.S.$ 0.7263 (U.S.$1.00 = $1.3769).

ADDITIONAL INFORMATION

A registration statement on Form F-10 will be filed by the Company with the SEC in respect of the offering of Securities. The registration statement, of which this prospectus constitutes a part, contains additional information not included in this prospectus, certain items of which are contained in the exhibits to such registration statement, pursuant to the rules and regulations of the SEC.

In addition to the Company's continuous disclosure obligations under the securities laws of certain provinces and territories of Canada, upon effectiveness of the registration statement on Form F-10, the Company will be subject to the information requirements of the *Exchange Act*, and in accordance therewith the Company will file with or furnish to the SEC reports and other information. The reports and other information that the Company files with or furnishes to the SEC will be prepared in accordance with the disclosure requirements of Canada, which differ in certain respects from those of the United States. As a foreign private issuer, the Company will be exempt from the rules under the *Exchange Act* prescribing the furnishing and content of proxy statements, and the Company's officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the *Exchange Act*. In addition, the Company may not be required to publish financial statements as promptly as U.S. companies. Copies of any documents that the Company has filed with the SEC are available to the public over the Internet at the SEC's website at www.sec.gov/edgar.

DOCUMENTS FILED AS PART OF THE REGISTRATION STATEMENT

The following documents have been or will be filed or furnished with the SEC as part of the registration statement on Form F-10 of which this prospectus forms a part: (i) the documents listed under the heading "*Documents Incorporated by Reference*"; (ii) powers of attorney from our directors and officers, as applicable; and (iii) the consent of KPMG LLP. A copy of the form of warrant, indenture, subscription receipt agreement or statement of eligibility of trustee on Form T-1, as applicable, will be filed by post-effective amendment or by incorporation by reference to documents filed or furnished with the SEC under the *Exchange Act*.

THE COMPANY

Name, Address and Incorporation

The Company was incorporated under the *Business Corporations Act* (British Columbia) on January 19, 2017 under the name "1104403 B.C. Ltd.". The Company changed its name to "NervGen Pharma Corp." on November 15, 2017.

The Company's head office is located at 112-970 Burrard Street, Unit 1290, Vancouver, British Columbia, V6Z 2R4 and its registered and records offices are located at 1133 Melville Street, Suite 3500, The Stack, Vancouver BC V6E 4E5, Canada.

On March 15, 2019, the Common Shares began trading under the symbol "NGEN" on the TSX-V. On May 3, 2019, the Common Shares began trading on the over-the-counter OTCQB® Venture Market under the symbol "NGENF".

Intercorporate Relationships

The Company has two wholly owned subsidiaries: 1) NervGen US Inc., which was incorporated in the State of Delaware on June 11, 2018; and 2) NervGen Australia Pty Ltd., which was incorporated in Australia on December 8, 2020. The Company does not hold securities in any other corporation, partnership, trust or other corporate entity.

DESCRIPTION AND GENERAL DEVELOPMENT OF THE BUSINESS

Overview of the Company

Neurologic trauma and neurologic disorders impose a major global health challenge, profoundly altering the lives of millions of people worldwide. Following neurologic trauma or the progression of neurologic disorders, the body responds via natural protective mechanisms, including the upregulation of an inhibitory class of molecules known as chondroitin sulfate proteoglycans ("**CSPGs**"), which prevent the nervous system from repairing itself. There are currently no approved therapies available that enable the nervous system to repair itself, or enable individuals to regain clinically meaningful measures of function, independence, or quality of life.

NervGen is a clinical-stage biopharmaceutical company developing first-in-class neuroreparative therapeutics for SCI and other traumatic and neurologic disorders. Our principal business activity is the discovery, development and commercialization of pharmaceutical products that may enable the nervous system to repair itself, with our initial focus on SCI. We are also utilizing our intellectual property and know-how to develop our products for other related medical conditions.

Our lead drug candidate, NVG-291, is currently being evaluated in our Phase 1b/2a CONNECT SCI Study for individuals living with SCI. NVG-291 has been granted Fast Track designation by the FDA and Orphan Drug Designation from the European Medicines Agency ("**EMA**"). We may also seek FDA Orphan Drug Designation and/or Breakthrough Therapy Designation, where appropriate, should our research indicate that such applications may assist in the development of our drug candidates.

We currently have no commercial products or services and do not generate operating revenues. The development of pharmaceutical products and the receipt of the necessary regulatory approvals required for commercialization typically involve lengthy and uncertain processes. As a result, no near-term revenues from product sales or services are expected.

Spinal Cord Injury

Spinal cord injury disrupts the transmission of signals between the brain and the body, resulting in partial or complete loss of motor, sensory, and/or autonomic function (such as bladder control) below the site of injury. SCI may occur at any level of the spinal cord and can be classified as either a complete injury, involving a total loss of sensation and

voluntary motor function below the injury site, or incomplete, in which partial neural signaling is preserved and limited sensory and voluntary motor function may remain below the level of injury.

In the majority of cases, SCI results from physical trauma, including falls, motor vehicle accidents, sports-related injuries, or other traumatic events. SCI may also arise from non-traumatic causes, such as infections, surgical complications, vascular insufficiency, tumours or underlying disease processes (e.g. stroke or demyelinating disorders).

According to data retrieved from the U.S. National Spinal Cord Injury Statistical Center[1]

- approximately 308,000 people are living with traumatic SCI in the United States;
- approximately 18,500 new traumatic SCI cases occur each year;
- the approximate average lifetime costs for people living with traumatic SCI ranges from U.S.$1.0 million to U.S.$6.0 million, depending on the severity of the injury and age; and
- the approximate average annual direct cost for people living with traumatic SCI after the first-year ranges from U.S.$55,000 to U.S.$250,000, depending on severity of the injury and age.

Recent Developments

In November 2025, we announced expanded clinical data from the Phase 1b/2a CONNECT SCI Study, showing that:

- Functional gains continued to increase at Week 16, four weeks after the end of treatment. NVG-291 participants demonstrated a 2.6-fold greater mean improvement in the Graded Redefined Assessment of Strength, Sensation and Prehension ("**GRASSP**") Total Score compared to placebo participants at Week 16.
- Hand function improvements were durable and further strengthened post-treatment, with NVG-291 participants experiencing a 3.7-fold greater mean improvement in GRASSP Quantitative Prehension compared to placebo participants at Week 16.

In addition, blinded, institutional-review board ("**IRB**") approved qualitative exit interviews were conducted up to 364 days after the conclusion of the study period to provide additional insight into participants' real-world experiences.

- NVG-291 participants reported more consistent, durable, and wide-ranging functional improvements than those receiving placebo, particularly in upper- and lower-limb function.
- 75% (6/8) of NVG-291 participants reported "much" or "very much" improved overall symptoms compared to 33% (3/9) of placebo participants as measured by the participant global impression of change scale.
- NVG-291 participants were more likely than placebo participants to report sustained improvements across key quality of life domains, including improved bladder control, reduced muscle spasticity, reduced reliance on medications or mobility aids, and greater physical activity tolerance.
    - 67% (6/9) of NVG-291 participants reported improved bladder control compared to 22% (2/9) on placebo.
    - 56% (5/9) of NVG-291 participants reported reduced muscle spasticity compared to 22% (2/9) on placebo.

NVG-291 demonstrated statistically significant reductions in upper and lower-limb reticulospinal tract signaling, as measured by startle motor evoked potential.

[1] NSCSC: Traumatic SCI Facts and Figures at a Glance; 2025 SCI Data Sheet.

- Legs (tibialis anterior): 142% greater reduction of hyperactive reticulospinal tract signaling compared to placebo (p=0.0062)

- Hands (first dorsal interosseus): 48% greater reduction of hyperactive reticulospinal tract signaling compared to placebo (p=0.0280)

Following SCI, the reticulospinal tract becomes hyperactive, compensating for impairment of the corticospinal tract.[2] When considered alongside previously reported statistically significant improvements in upper-limb corticospinal connectivity, we believe these expanded electrophysiological findings establish the biological basis for NVG-291's clinical efficacy and believe that the efficacy signal observed in the chronic cohort of the Phase 1b/2a CONNECT SCI Study supports the clinical advancement of NVG-291 in chronic SCI.

In November 2025, we also announced that we completed an FDA Type C meeting in September to discuss clinical development plans and the potential for accelerated approval. The FDA confirmed that multiple regulatory pathways are available to support approval, given the significant unmet medical need among individuals living with SCI and the lack of any approved pharmacologic treatments. We anticipate holding an End-of-Phase 2 meeting in early 2026 to further align with the FDA on the development and registration pathway for NVG-291.

On November 19, 2025, we completed the Private Placement of 4,785,674 units at a price of U.S.$2.10 per unit for aggregate gross proceeds of U.S.$10,049,915. Each unit consisted of one Common Share and one-half of one Warrant. The Warrants are valid for 36 months following closing of the Private Placement and each Warrant is exercisable into one Common Share at an exercise price of U.S.$2.65.

Further details concerning our business, including information with respect to our assets, operations, research, and development history, are provided in our AIF, Annual MD&A, Interim MD&A and the other documents incorporated by reference into this prospectus available on SEDAR+ at www.sedarplus.ca. and EDGAR at www.sec.gov/edgar. See "*Documents Incorporated by Reference*".

RISK FACTORS

Before making an investment decision, prospective purchasers of Securities should carefully consider the information described in this prospectus, any applicable prospectus supplement and the documents incorporated by reference herein and therein. Additional risk factors relating to a specific offering of Securities may be described in the applicable prospectus supplement. Some of the risk factors described herein, in any applicable prospectus supplement and in the documents incorporated by reference herein and therein, are interrelated and, consequently, investors should treat such risk factors as a whole. If any event arising from these risks occurs, our business, prospects, financial condition, results of operations and cash flows, and your investment in the Securities could be materially adversely affected. Additional risks and uncertainties of which we currently are unaware or that are unknown or that we currently deem to be immaterial could have a material adverse effect on our business, financial condition and results of operation. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part. We cannot assure you that we will successfully address any or all of these risks. For additional information in respect of the risks affecting our business, see the section "Risk Factors" of our Annual Information Form, which is incorporated herein by reference and available under our profile on SEDAR+ at www.sedarplus.ca.

Risks Related to Our Financial Position, Need for Additional Capital and Limited Operating History

We have a limited operating history, are early in our development efforts, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any revenue from

[2] Akalu et al., (2023) Physiological reports, 11(14), e15765.

product sales. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. In October 2023, we initiated a CONNECT SCI Study evaluating NVG-291 in individuals with spinal cord injury, or SCI, which is the most advanced product candidate in clinical development. To date, we have devoted substantially all of our resources and efforts to developing our product candidates, building our intellectual property portfolio, business planning, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully initiate or complete any pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage pharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

Since our inception, we have incurred significant net losses and expect to continue to incur significant net losses for the foreseeable future and we may never achieve or maintain profitability.

We have incurred significant net losses since our inception and have financed our operations principally through equity financings. Our net loss was $17.2 million and $15.6 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $119.9 million. Given that our lead product candidate, NVG-291 for the treatment of SCI is in active clinical development, and our other programs are in preclinical or discovery stages, we expect that it will be several years, if ever, before we receive approval to commercialize a product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance, particularly since we expect our expenses to increase if and when our product candidates progress through clinical development as product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. We expect such net losses to increase substantially as we continue our research and development of, and seek regulatory approvals for, our lead product candidates and any other current or future product candidates. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and, following the completion of any offering, the performance of our share price.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for our lead product candidates and advance our other programs. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities.

Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, the FDA, the European Medicines Agency, the EMA, Health Canada, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We are not permitted to market or promote NVG-291 for SCI or any other indication, or any other product candidate we are developing, before we receive marketing approval from the FDA or other comparable regulatory authority.

As of September 30, 2025, we had $11.4 million in cash and cash equivalents and received $14.5 million since September 30, 2025 in net proceeds from the Private Placement and warrant and option exercises. We have forecasted that our ability to operate our business as currently conducted for the ensuing 12 months is dependent on raising additional financing. Alternatively, if measures are taken to reduce operating costs, delay planned expenditures in our research and development programs and slow the progress in our planned clinical programs, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the date of this prospectus, which forecast takes into account any fees payable over the next 12 months pursuant to the Company's license agreement with Case Western Reserve University ("**Case Western**"). We will need to raise additional capital to complete the development and commercialization of our products. Our estimate as to how long we expect our existing cash and cash equivalents, to be able to continue to fund our operations is based on assumptions that may prove to be inaccurate, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our future capital requirements, both short- and long-term, will depend on a variety of factors, including, but not limited to:

- the scope, timing, costs, rate of progress, and results of our discovery research, results from our preclinical studies including toxicology, and results of our clinical trials including later stage clinical trials;
- the number and scope of preclinical studies and clinical trials that we pursue;
- the cost, timing, and outcome of seeking and obtaining approvals by the FDA, EMA, Health Canada and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or for such authorities to change their requirements on studies that had previously been agreed to;
- our ability to establish licensing or collaboration agreements or other strategic agreements;
- the achievement of milestones or other developments that result in obligations under any collaboration agreements we may enter into in the future;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements we have entered into and may enter into in the future;
- the cost of establishing, maintaining, expanding, enforcing, and defending the scope of our intellectual property portfolio;
- the cost of acquiring, licensing, or investing in additional businesses, products, product candidates, and technologies that we may identify;
- the cost of manufacturing or to have manufactured and our ability to manufacture sufficient, reliable, timely, and affordable supply of materials in accordance with current good manufacturing practices, or cGMP, that can be used in clinical trials and potential commercial sales;

- the cost of commercializing product candidates, if approved, whether alone or in collaboration with others;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of building or contracting sales, marketing, and/or distribution capabilities, systems, and internal infrastructure if or when we obtain regulatory approvals for a product candidate;
- the impact of competitors' product candidates and technological advances and other market developments;
- the expenses needed to attract and retain skilled personnel; and
- the size of the markets and degree of market acceptance of any product candidates in territories in which we receive regulatory approval, including product pricing, product coverage, and the adequacy of reimbursement by third-party payors.

A change in the outcome of any of these factors or underlying variables with respect to the development of a product candidate or future product candidate could significantly change the costs and timing associated with the development of that product candidate. Our business plans may change in the future and we will continue to require additional capital to meet the needs of our operating expenses. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts.

Positive results from early preclinical studies and clinical trials of our current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our current or future product candidates. If we cannot replicate the positive results from our preclinical studies or early clinical trials of our current or future product candidates, we may be unable to successfully raise sufficient financing to develop, obtain regulatory approval for and commercialize our current or future product candidates.

Positive results from preclinical studies and early clinical trials of our current or future product candidates, including our ongoing clinical trial of NVG-291, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of our current or future product candidates according to our current development timeline, the positive results from such preclinical studies and/or clinical trials of our current or future product candidates, including NVG-291, may not be replicated in subsequent preclinical studies or clinical trials. In particular, while the topline data from the chronic cohort of our ongoing Phase 1b/2a clinical trial of NVG-291 demonstrated promising efficacy signals, we do not know whether NVG-291will perform similarly in the subacute cohort of our ongoing Phase 1b/2a clinical trial or in subsequent clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the FDA or comparable foreign regulatory authority. If we fail to produce positive results in our planned or ongoing preclinical studies or clinical trials of any of our current or future product candidates, our ability to obtain adequate financing and the development timeline and regulatory approval and commercialization prospects for such current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

We have a history of negative operating cash flow and may continue to experience negative operating cash flow.

Since our incorporation in January 2017, we have generated negative operating cash flows. We anticipate that we will continue to have negative cash flow and we expect to continue to incur losses for the foreseeable future as we continue to research and develop, and seek regulatory clearances for, our current product candidate and other potential product candidates. To the extent that we have negative operating cash flow in future periods, we may need to allocate a

portion of our cash reserves to fund such negative cash flow. We may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that we will be able to generate a positive cash flow from our operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favourable to us.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private party grants, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include rights or preferences that adversely affect your rights as a holder of Common Shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

We have net operating loss carryforwards in Canada, the United States and internationally which could expire unused and become unavailable to offset future income tax liabilities. The rules dealing with Canadian and U.S. federal, provincial, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Canada Revenue Agency, Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws, or changes in interpretations of existing laws (which changes may have retroactive application), including with respect to net operating losses and tax credits, could adversely affect us or holders of our Common Shares. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, NVG-291, which is currently in a Phase 1b/2a clinical trial for SCI. If we are unable to complete development of, obtain approval for and commercialize NVG-291 for SCI in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely complete clinical trials, the results of those trials, the results of all preclinical studies which include toxicology, our ability to manufacture product using third party partnerships and our ability to obtain marketing approval for and successfully commercialize NVG-291 for SCI, our lead product candidate. We have invested, and continue to invest, significant efforts and financial resources in the research and development of NVG-291 for SCI as well as potential other indications. We are currently conducting a Phase 1b/2a trial that aims to demonstrate the efficacy, safety, and tolerability of NVG-291 for SCI. NVG-291 will require additional clinical development and evaluation of clinical results from those trials, preclinical studies including toxicology and manufacturing activities, regulatory submission, marketing approval from government regulators, substantial investment and significant marketing efforts before we can generate any revenues from product sales. In addition, because our lead product candidate is our most advanced product candidate, if NVG-291 for SCI encounters safety or efficacy problems, manufacturing or supply interruptions, developmental delays, regulatory issues, or other problems, our development plans and business related to other indications for NVG-291 could be significantly harmed. We are not permitted to market or promote NVG-291 for SCI or any indication, or any other product candidate we are

developing, before we receive marketing approval from the FDA and comparable non-U.S. regulatory authorities, and we may never receive such marketing approvals.

Our ability to generate revenue and achieve profitability depends significantly on several factors, including but not limited to the following:

- successful outcomes of and timely completion of nonclinical and clinical development of our product candidates and any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of nonclinical study or clinical trial delays due to any public health emergencies or other causes;

- our ability to remove or mitigate the impact of the partial clinical hold imposed by the FDA;

- the initiation and successful recruitment of subjects and completion of additional clinical trials on a timely basis;

- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the United States and other countries, of our product candidates and any future product candidates;

- the frequency and severity of adverse events in the clinical trials;

- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, the EMA, Health Canada or any comparable foreign regulatory authority for marketing approval;

- developing complete regulatory submissions, including information related to the preclinical, clinical and, CMC development of any product candidates;

- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;

- completing any required post-marketing approval commitments to applicable regulatory authorities;

- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale and meet other cGMP requirements;

- establishing and maintaining commercially viable supply, manufacturing, and distribution relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;

- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;

- a continued acceptable safety profile following any marketing approval of our product candidates and compliance with any post-market safety-related requirements;

- commercial acceptance of our product candidates by patients, the medical community and third-party payors;

- identifying, assessing and developing new product candidates;

- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and other countries;

- protecting our rights in our intellectual property portfolio;

- defending against third-party interference or infringement claims, if any;

- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;

- obtaining coverage and adequate reimbursement by hospitals, government and third-party payors for product candidates that we develop;

- addressing any competing therapies and technological and market developments; and

- attracting, hiring and retaining key personnel, including research and development personnel, quality and regulatory personnel, manufacturing and technical operations personnel and future commercial personnel.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the development, manufacturing, marketing, distribution, and sales efforts of any future collaborator. We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability.

There are currently no FDA-approved products for the treatment of SCI.

There is currently no FDA-approved therapeutic for the treatment of SCI. We have not received regulatory approval for NVG-291, and cannot be certain that our approach will lead to the development of an approvable or marketable product, alone or in combination with other therapies. We may not succeed in demonstrating the safety and efficacy of NVG-291 in our ongoing clinical trials or in larger-scale clinical trials.

The regulatory approval processes of the FDA, EMA, Health Canada and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to commercialize our product candidates and generate product revenue and our business will be substantially harmed.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many non-U.S. jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;

- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;

- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable non-U.S. regulatory agency for marketing approval;

- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may not accept data generated from our preclinical studies and/or clinical trial sites, or may require that we conduct additional non-clinical or clinical trials;

- the population studied in the clinical trial may not be sufficiently broad or representative of the real-world population to assure efficacy and safety in the full population for which we seek approval;

- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials, or may not approve the formulation, labeling or specifications of any of our current or future product candidates;

- the data collected from manufacturing and testing, preclinical studies, or clinical trials of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, other submission or to obtain regulatory approval in the United States or elsewhere;

- we may be unable to demonstrate to the FDA, EMA, Health Canada or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;

- if an advisory committee is needed to review our marketing application submitted to the FDA, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend a conditional approval or additional non-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- contract research organizations, or CROs, that we retain to conduct our non-clinical or clinical studies may take actions outside of our control that materially adversely impact our business operations or clinical development plans;

- the FDA or the applicable non-U.S. regulatory agency may be delayed in their review processes due to staffing shortages, government shutdown, or other restrictions or government policies that may impact its resources and operations; and

- the approval policies or regulations of the FDA, EMA, Health Canada or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our current or future product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects. Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting

prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement, and we have had limited interactions with foreign regulatory authorities. The foreign regulatory approval process varies among countries and may include all of the risks associated with obtaining FDA approval described above as well as risks attributable to the satisfaction of local regulations in non-U.S. jurisdictions. We may not obtain regulatory approvals in any jurisdiction on a timely basis, if at all. We may not be able to file for regulatory approvals, and, even if we file, we may not receive the necessary approvals to commercialize our products in any market, which will prevent us from marketing our products internationally and have an adverse effect on our business and financial condition. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

Preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates.

Before obtaining marketing approval from the FDA, EMA, Health Canada or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We do not know whether our future clinical trials will begin on time or enroll subjects on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable non-U.S. regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;

- subjects failing to enroll or remain in our trial at the rate we expect, or failing to adhere to the clinical trial protocol or return for post-treatment follow-up;

- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;

- lack of adequate funding to continue the clinical trial;

- subjects experiencing severe or unexpected drug-related adverse effects;

- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;

- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;

- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable non-U.S. regulatory authorities to temporarily or permanently shut down or voluntarily shutting down or reducing capacity due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

- any changes to our manufacturing process that may be necessary or desired or additional manufacturing work required to support the stability of product candidates or verify or validate manufacturing processes;

- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice, or GCP, or other regulatory requirements;

- third-party contractors not performing data collection or analysis in a timely or accurate manner; or

- company employees or third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Disruptions caused by public health emergencies may also increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable non-U.S. regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, unfavorable inspection of the clinical trial operations or trial site resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects or failure to demonstrate a benefit from using a drug. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA, comparable non-U.S. regulatory authorities, or other government. The FDA or comparable non-U.S. regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable non-U.S. regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable non-U.S. regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could delay or prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences. NVG-291 for SCI is currently subject to a partial clinical hold by the FDA, and we may be unable to have the hold removed which could adversely affect development of NVG-291 and our results of operations.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us, an IRB, a Data Safety Monitoring Board, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable non-U.S. regulatory authorities. For example, a partial clinical hold was placed on NVG-291 by the FDA in March 2020 when adverse dose-dependent reproductive organ toxicity results were observed in initial 7-day and 28-day preclinical animal toxicology studies. Under the partial clinical hold, we were permitted to enroll postmenopausal females in the single ascending dose and multiple ascending dose portions of the study, respectively. After we completed the preclinical studies requested by the FDA, in October 2022, the FDA amended the partial clinical hold to permit the inclusion of males and premenopausal females at certain dose levels in our Phase 1 clinical trial of NVG-291. The additional preclinical safety studies requested by the FDA will further investigate the preclinical safety margin of NVG-291, testing exposures of NVG-291 higher than those tested in the follow-up preclinical safety studies and for longer durations to enable chronic dosing greater than 3 months. These 6-month chronic toxicity preclinical studies are required to gain marketing approval but could result in unexpected negative results which could impact our ability to dose for longer durations or at higher dose levels deemed necessary for efficacy. If we are unsuccessful in removing the partial hold and we later determine that the permitted dose levels are insufficient to show clinical efficacy of NVG-291 for SCI, our development of NVG-291 may be adversely affected.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Subjects in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Subjects treated with our product candidates may also be undergoing other treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting participants to the clinical trials, subjects may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, Health Canada, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product candidate from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, Health Canada or other comparable foreign regulatory authorities.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, including NVG-291, we will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. We do not know whether NVG-291 or our potential future product candidates will perform in current or future clinical trials as in preclinical studies or early clinical studies. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, Health Canada and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the study populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Subjects treated with our product candidates may also be undergoing other treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a given individual, and from subject to subject and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, in June 2025 we announced positive topline data from the chronic cohort of our ongoing Phase 1b/2a clinical trial of NVG-291. However, there can be no assurance that the final topline data from the trial will be consistent with such results or otherwise viewed as positive. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all

data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. Adverse differences between preliminary or interim data and final data could significantly harm our prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Common Shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial, is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differs from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition.

If we fail to develop and commercialize NVG-291 for additional indications or fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of NVG-291 for the treatment of SCI is our primary focus, as part of our longer-term growth strategy, we have also conducted preclinical test of concept evaluation of NVG-300-R in animal models of stroke and SCI. We intend to evaluate internal opportunities potentially provided by NVG-291, NVG-300 or other potential product candidates, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable non-U.S. regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. If we are unsuccessful in identifying and developing additional product candidates, our potential for growth and achieving our strategic objectives may be impaired.

We may expend our limited resources to pursue a particular product or indication and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued. As a result, we may forgo or delay pursuit of other opportunities with others that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield, minimize costs and achieve consistent quality and results. For example, the manufacturing process used to produce clinical supplies for our clinical trials may be different from that used in prior or future trials, and we may use a different supplier or contract manufacturer for commercial supplies after regulatory approval. There can be no assurance that such changes will achieve the intended objectives. These changes and any future changes we may make to any product candidates may also cause such candidates to perform differently and affect the results of future clinical trials conducted with the modified materials. Such changes or related unfavorable clinical trial results could delay initiation or completion of additional clinical trials, require the conduct of comparability bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential marketing approval and jeopardize our ability to commercialize the affected product candidates, if approved, and generate revenue. There can be no assurance that FDA, EMA, Health Canada, or comparable regulatory authorities will accept our conclusions that any such changes did not have an adverse effect on the product candidate or that such changes may negatively impact the interpretation of the study data.

If we are unable to successfully develop companion diagnostics or biomarkers that may be required for our therapeutic product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates.

We may develop companion diagnostics or biomarkers for our therapeutic product candidates. It is expected that, at least in some cases, regulatory authorities may require the development and regulatory approval of a companion diagnostic or biomarkers as a condition to approving a therapeutic product candidate. We have limited experience and capabilities in developing or commercializing diagnostics or biomarkers and plan to rely in large part on third parties to perform these functions. We do not currently have any agreement in place with any third party to develop or commercialize companion diagnostics or biomarkers for any of our therapeutic product candidates.

Companion diagnostics or biomarkers are subject to regulation by the FDA, EMA, Health Canada and comparable foreign regulatory authorities and may require separate regulatory approval or clearance prior to commercialization. If we, or any third parties that we engage to assist, are unable to successfully develop companion diagnostics or biomarkers for our therapeutic product candidates, or experience delays in doing so, our business may be substantially harmed.

If we experience delays or difficulties in the enrollment and/or retention of participants in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Subject enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. In particular, for our trials in SCI, participants are difficult to enroll given the nature of their injuries and the need to travel for treatment. In the past we have encountered enrollment delays and may experience additional delays in the future. As such, we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials to such trial's conclusion as required by the FDA, EMA, Health Canada or other comparable foreign regulatory authorities. Additionally, certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible subjects or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Subject enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and subjects who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Subject enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- the ability to enroll subjects quickly after SCI for our subacute study population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- subject eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor subjects adequately during and after treatment;
- proximity and availability of clinical trial sites for potentially interested study participants;
- continued enrollment of prospective subjects by clinical trial sites; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of subjects for our clinical trials, we may have difficulty maintaining enrollment of such subjects in our clinical trials.

As an organization, we have never conducted later-stage clinical trials or submitted a new drug application, and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates, and we will need to successfully complete pivotal clinical trials in order to seek approval from the FDA or other non-U.S. regulatory authority to market NVG-291 or any future product candidates we may develop. Carrying out clinical trials and the submission of new drug applications, or NDAs, is complicated. As an organization, we have not conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting, and prosecuting regulatory filings and have not previously submitted an NDA or other applicable non-U.S. regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we cannot be certain how many clinical trials of our product candidates will be required or how such trials will have to be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop. In addition, we may need to enter into arrangements with collaborators or others to conduct, or assist us in conducting, such clinical trials and we may not be successful in entering into arrangements with third parties to conduct, or assist us with conducting such clinical trials, or may be unable to do so on terms that are favorable to us. If we engage such third parties, our product revenues and our profitability, if any, could be lower than if we were to clinically develop product candidates ourselves, we may have

little control over such third parties and any of them may fail to devote the necessary resources and attention to conduct such clinical trials effectively. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing our product candidates.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. Our competitors are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

There are currently no approved pharmaceutical products that enable sustained improvements in function for people with SCI. There are a number of mobility assistance and neuro stimulation devices in development or approved to improve quality of life for individuals living with SCI.

There are a significant number of approved therapies for multiple sclerosis ("**MS**") and fewer approved for stroke, but they all target the immune system in one way or another (immunomodulatory or immunosuppressive). There are several treatments approved for stroke, which are either preventive (antiplatelet or anticoagulant) or require acute intervention and are focused on early revascularization (e.g. tissue plasminogen activator). There are no approved therapies that promote neural repair (e.g. remyelination, plasticity) for either MS or stroke.

There are several clinical trials underway evaluating experimental treatments for SCI, stroke and MS.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data emerge. Competitors, independently or through collaboration, are developing products that potentially directly compete with our current or future product candidates and which may either be a longer lasting or a more efficacious treatment or receive FDA or other applicable regulatory approval more rapidly than our current or future product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Fast Track or Breakthrough Therapy designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates.

We may seek Fast Track or Breakthrough Therapy designation from the FDA for some or all of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with such designations. The FDA's Fast Track and Breakthrough Therapy designation programs are intended to expedite the development of

certain qualifying product candidates intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the product's potential to address an unmet medical need for this condition, the sponsor may apply for FDA Fast Track designation.

A product candidate may be designated as a breakthrough therapy if it is intended, alone or in combination with one or more other drugs or biologics to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

We have received Fast Track designation for NVG-291 in individuals with SCI. While we may seek Fast Track or Breakthrough Therapy designation for some or all of our product candidates, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Fast Track or Breakthrough Therapy designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular time frame. For example, although we have received Fast Track designation for NVG-291 in individuals with SCI, there can be no guarantee that we will receive marketing approval or that approval will be granted on an accelerated time-frame. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track and/or Breakthrough Therapy designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs and biologics that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs and biologics intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug or biologic in Europe would be sufficient to justify the necessary investment in developing the drug or biologic. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug or biologic is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency, or EMA, or the FDA from approving another marketing application for the same drug and for the same indication during the period of exclusivity, except in limited circumstances. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be

reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect such product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug or biologic is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designation, there is no guarantee that we will enjoy the benefits of that designation.

Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including, but not limited to:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any one or more of our product candidates are approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

Our estimates of the potential market opportunity for NVG-291 for the treatment of SCI as well as any other product candidates include several key assumptions based on our industry knowledge, industry publications and third-party research reports. There can be no assurance that any of these assumptions are, or will remain, accurate. If the actual market for NVG-291 for SCI or other indications, or for any other product candidate we may develop, is smaller than we expect, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be successful in commercializing our product candidates that obtain regulatory approval.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we obtain marketing approval, and for which we decide to independently commercialize, we will need to establish a sales and marketing organization or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we do not establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, could be lower than if we were to market, sell and distribute any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks Related to Our Dependence on Third Parties

Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities of such materials on time or at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for the development, manufacture and supply of the active pharmaceutical ingredients, or APIs, in our product candidates. We have not made large scale up batches required for commercialization and NVG-291 is a large peptide that requires specialists in manufacturing and development of which we outsource. Our current strategy is to continue to outsource all manufacturing of our product candidates to third parties.

We currently engage third-party manufacturers to provide the APIs of NVG-291 and for the final drug product formulation of NVG-291 that is being used in our clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture NVG-291, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of NVG-291, and the costs of manufacturing could be prohibitive.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA, EMA, Health Canada and other foreign regulatory authorities.

If NVG-291 for SCI or potential additional indications or any other product candidate is approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of

manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA and corresponding non-U.S. regulators. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable non-U.S. regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA, Health Canada and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA, EMA, Health Canada and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding non-U.S. regulators also inspect these facilities to confirm compliance with cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA, Health Canada and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely on third parties, such as CROs, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Moreover, the FDA requires us to comply with GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, EMA, Health Canada or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

We may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the

functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not perform their obligations as expected;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;

- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

We may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We

cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they may have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

Risks Related to Legal and Regulatory Compliance Matters

Even if our product candidates receive regulatory approval, they will be subject to significant post marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or non-U.S. regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, failure to comply with FDA, EMA, Health Canada and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;

- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or maintain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including the FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue, could require us to expend significant time and resources in response and could generate negative publicity.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA, EMA or Health Canada grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the product candidate based on their own review of its clinical development, manufacturing, marketing and promotion and reimbursement. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as preclinical studies or clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We have conducted and may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, EMA, Health Canada or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from clinical trials outside the U.S. are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means, if the FDA deems it necessary. Additionally, the FDA's clinical trial requirements, including the adequacy of the study population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, Health Canada or any applicable foreign regulatory authority will accept data from trials conducted outside of their applicable jurisdiction. If the FDA, EMA, Health Canada or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; and cost-effectiveness data.

Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products reimbursed by certain federal healthcare programs are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. In addition, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately where coverage is available, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or maintain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively, the "**ACA**"), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services Secretary, the HHS Secretary, as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care organizations. The ACA also established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. In December 2020, the CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products, which could have a material impact on our business.

Since the ACA's passage, legislative changes to the ACA have been proposed and adopted. On July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act," or OBBBA, was signed into law which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-

directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA's enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. Additionally, under the sequestration required by the Budget Control Act of 2011, beginning April 1, 2013, Medicare payments to providers were reduced, which will remain in effect through 2032 unless additional Congressional action is taken. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate effective January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Further, there has been increasing legislative and enforcement interest in the United States aimed at increasing transparency of drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs. In particular, in August 2022, Congress passed the Inflation Reduction Act, or IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Further, uncertainties created by the IRA and other cost containment measures may negatively impact potential investments, company valuation, royalty-based earnings, mergers and acquisitions in our industry.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status are attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Our ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product, which was originally approved in 2000, and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, our ability to develop current or future product candidates we may develop may be at risk and could be delayed, undermined or subject to protracted litigation. Finally, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which

for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as FDA acted within its statutory authority under the Administrative Procedure Act (the "**APA**"). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Centers for Medicare & Medicaid Services that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state and non-U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal false claims, including the civil False Claims Act, the FCA, that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct;

- the Federal Health Insurance Portability and Accountability Act of 1996, HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, also known as the CMS Open Payments, and its implementing regulations, which require manufacturers of covered drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value

made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and non-U.S. laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical and/or medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical and/or medical device products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs, as such laws and regulations may also become more complex over time. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Failure to comply with laws, rules, regulations, policies, industry standards and contractual obligations relating to privacy, data protection and data security could adversely affect our business.

We collect, maintain and otherwise process a large quantity of data relating to our employees and in connection with our clinical trials, and we face risks inherent in both handling large volumes of data and in protecting the security of such data. Our data processing activities subject us to numerous laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other actual and asserted obligations relating to privacy, data protection and data security. Our actual or perceived failure to comply with any such actual or alleged obligations could result in enforcement actions and other claims, demands and proceedings that may negatively impact our revenue, as well as expose ourselves to criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings. In Canada, where we are headquartered, federal and provincial legislation impose strict requirements for the processing of personal data of individuals, with substantial penalties for noncompliance. In the United States, both federal and various state governments have adopted, or are considering, laws, guidelines or rules for the collection, distribution, use and storage of information collected from or about individuals. Many of the state laws differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, the CCPA, which went into effect on January 1, 2020 and was amended by the California Privacy Rights Act of 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches. Although the CCPA exempts some data processed in the context of clinical trials and exempts protected health information, as defined by HIPAA, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws have been enacted in several other states, such as Virginia, Connecticut, Colorado, Utah, Iowa, Indiana, Montana, Tennessee, Florida, Oregon, Delaware, Texas and New Jersey, and proposed in other states and at the federal level. In addition to these consumer privacy laws, in April 2023, the state of Washington enacted the My Health My Data Act, which went into effect in March 2024. This new law imposes strict requirements on the collection, use and processing of health-related information that is not subject to HIPAA, and provides for a private right of action. The Washington law adds additional complexity to our existing compliance obligations and may increase our potential liability relating to our collection and processing of health-related information.

Outside of the United States, certain foreign jurisdictions, including the European Economic Area, EEA, and the United Kingdom have laws and regulations which are more restrictive in certain respects than those in the United States. For instance, the collection and use of personal data, including health data, in the EEA is governed by the

General Data Protection Regulation, in the UK by the UK General Data Protection Regulation, (collectively "**GDPR**"). The GDPR, and national implementing legislation in EEA member states and the United Kingdom, impose a strict data protection compliance regime which tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Actual or alleged failure to comply with the GDPR may result in regulatory inquiries and other proceedings by regulatory authorities and, in certain cases, private individuals and may result in substantial fines and other administrative penalties, restrictions upon our data processing activities and other liabilities. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to address the GDPR's requirements. We may incur liabilities, expenses, costs, and other operational losses under the GDPR and local laws of nations included within the EEA, the UK, and other regions in connection with any measures we take to comply with them. Working to comply with the GDPR and other laws and regulations to which we are subject in the EEA, UK, and other regions outside the United States relating to privacy, data protection and data security will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our activities in those regions, and our business could be adversely affected.

Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals' privacy rights, failed to comply with laws, regulations, contractual obligations or other actual or asserted obligations relating to privacy, data protection or data security, even if resolved in our favor, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties to perform laboratory work and for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Changes in the leadership of the FDA and other federal agencies and other policies implemented by the federal administration may lead to changes in the operations of the FDA, which may have a material impact on the industry and our clinical development plans.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs or if a significant number of federal employees are laid off or leave federal agencies, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to advance clinical development of our product candidates.

In addition, government funding of the Securities and Exchange Commission and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. If a prolonged government shutdown or other disruption occurs, or if global health or other concerns continue to prevent regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are subject to certain U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, (collectively, the "**Trade Laws**"), prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We currently engage third parties for clinical trials and research and development activities and have obtained, or intend to obtain, necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.

We are developing NVG-291 pursuant to the license agreement with Case Western and may develop other early stage preclinical or discovery drug candidates. We are subject to a number of risks associated with our agreement with Case Western, including the risk that Case Western may terminate the license agreement upon the occurrence of certain specified events. The license agreement requires, among other things, that we make certain payments and use reasonable commercial efforts to meet certain business, preclinical, clinical and regulatory milestones. If we fail to comply with any of these obligations or otherwise breach this or similar agreements, the licensor may have the right to terminate the license in whole. Loss of our rights to the licensed intellectual property from Case Western or any similar license granted to us in the future, or the exclusivity rights provided therein, can harm our financial condition and operating results.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours including upon expiration of any applicable regulatory exclusivity. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent and other intellectual property protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others, and maintain trade secret protection of technologies.

We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies, and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

We currently own or in-license issued and pending patents directed to the composition of the product candidates that we have thus far developed. Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to their method of use or production process. However, we cannot be certain that any claims in our patent applications directed to the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in countries outside the U.S., or that, if issued, the claims in any such patents, if challenged, will be adjudicated to be not invalid and enforceable by courts and administrative bodies in the U.S. or other countries. Further, if issued, any composition of matter patents covering our product candidates may expire at such a date that competitors may not be prevented from developing, making and marketing a product identical to our product candidates after expiration of any applicable regulatory exclusivities.

Method of use patents protect the use of a product for the specified method or indication. This type of patent does not prevent a competitor from making and marketing a product identical to our product candidate for an indication that is outside the scope of the patented methods of use. Moreover, even if competitors do not actively promote their product for indications covered by our patents, clinicians may prescribe these competitor products "off-label" for uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. To establish our proprietary position, we own and have in-licensed certain intellectual property rights, and we and our licensors have filed and may file provisional and non-provisional patent applications in the U.S. or abroad relating to our product candidates and certain technologies that are important to our business.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our future licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding patent applications and patent applications in certain non-U.S. territories, or those of our future licensors, will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in other countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom may have substantially greater resources than we do and many of whom may have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- there may be significant pressure on the U.S. government and other governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing non-U.S. competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review and *inter partes* review, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our future licensors may become subject to post-grant challenge proceedings, such as oppositions in a patent office outside of the U.S., that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent

expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

A third party or former employee or collaborator may claim an inventorship or ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third-parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Further, regardless of the outcome, if we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidate without infringing the intellectual property and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates, including patent infringement lawsuits in the US or abroad, as well as interference, derivation, *inter partes* review, and post-grant proceedings before the USPTO and opposition or other proceedings before corresponding patent offices outside of the U.S. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent

litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our future licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include patent ineligibility, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, indefiniteness, and/or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution with intent to deceive the USPTO.

Our patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review or *inter partes* review, derivation proceedings, and equivalent proceedings in other jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we

would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be

forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in U.S. patent law, or laws in other countries, or their interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other non-U.S. legislative bodies may pass patent reform legislation that is unfavorable to us.

Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application would be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included several significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned and in-licensed patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

U.S. law relating to the patentability of certain inventions in the life sciences is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future. The U.S. Supreme Court and federal courts have ruled on several patent cases in recent years that impact the scope of patentability of certain inventions or discoveries related to the life sciences, including both narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products, and could jeopardize or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable our patent rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For example, the U.S. Supreme Court recently held in *Amgen v. Sanofi (2023)* that a functionally claimed overly broad genus claim without sufficient data support was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Additionally, other decisions in prior years found that patent claims that recite laws of nature are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a "sufficient" additional feature is uncertain. Depending on future actions and/or decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future.

In 2012, the European Union Patent Package, the EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("**UPC**") for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

We may not be able to protect or enforce our intellectual property rights throughout the world.

Although we have pending patent applications in the United States and other countries, filing, prosecuting and defending patents and trademarks on all of our planned products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing our patented products in and into other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our future licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or our future licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our future licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially

diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geo-political actions in the United States and in other countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement or defense of our issued patents which could impair our competitive intellectual property position.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market.

Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions assignment agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of any future licenses granted to us by others.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

We depend heavily on our executive officers, principal consultants and others, and the loss of their services would materially harm our business.

Our success depends, and will likely continue to depend, upon our ability to hire, retain the services of our current executive officers, principal consultants and others, including our President and Chief Executive Officer, our Chief Medical Advisor, and our Chief Financial Officer. We have entered into employment or consulting agreements with each of the key members of our executive, scientific and operating staff, but they may terminate their employment with us at any time. The loss of their services might impede the achievement of our discovery research, preclinical development, manufacturing and technical operations and commercialization objectives.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of

turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific, regulatory, financial and clinical advisors, to assist us in formulating our research and development and commercialization strategy and capitalization plans. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We only have a limited number of employees to manage and operate our business.

As of September 30, 2025, we had 13 full or part-time employees. Our focus on the development of NVG-291 for SCI and the future development of NVG-300 requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop NVG-291 for SCI or any other indication or to develop NVG-300 or other exploratory drug candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

Our future growth may depend, in part, on our ability to operate internationally, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our programs in international markets for which we may rely on collaboration with third parties. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- potential failure to obtain regulatory approvals for the sale or use of our product candidates in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if we or our collaborators do not execute successfully;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, including the military conflict between Russia and Ukraine and the war between Israel and Hamas, public health emergencies, including pandemics, boycotts, curtailment of trade and other business restrictions; and

- uncertainty regarding tariffs and the potential for tariffs to trigger a global trade war;

- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities.

Any of these risks, if encountered, could have a material adverse effect on our financial condition, results of operations and cash flows.

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Risks Related to Ownership of Our Securities

The market price of our Common Shares may be volatile, and you could lose all or part of your investment.

The trading price of our Common Shares is likely to continue to be volatile and could be subject to fluctuations in response to various factors, some of which are beyond our control. These fluctuations could cause you to lose all or part of your investment in our Common Shares since you might be unable to sell your shares at or above the price you paid in any offering. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, factors that could cause fluctuations in the trading price of our Common Shares include the following:

- the timing and results of preclinical studies and clinical trials of our product candidates, those conducted by third parties or those of our competitors;

- the success of competitive products or announcements by potential competitors of their product development efforts;

- regulatory actions with respect to our products or our competitors’ products;

- actual or anticipated changes in our growth rate relative to our competitors;

- regulatory or legal developments in the United States, Canada and other countries;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel;

- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- the public's reaction to our press releases, other public announcements and filings;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our Common Shares by us, our insiders or our other shareholders;
- the impact of any natural disasters or public health emergencies, including pandemics;
- general economic, political, industry and market conditions including the impact of increasing inflation;
- rumors and market speculation involving us or other companies in our industry;
- litigation involving us, our industry or both;
- expiration of market stand-off or lock-up agreements; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have an adverse impact on the market price of our Common Shares.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Sales of a substantial number of shares of our Common Shares in the public market could cause our share price to fall.

Sales of a substantial number of shares of our Common Shares in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Shares and could impair our ability to raise capital through the sale of additional equity securities. In the future, we may issue additional Common Shares or other equity or debt securities convertible into Common Shares in connection with a financing, acquisition, litigation settlement, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause our share price to decline.

If we successfully list our Common Shares on the Nasdaq, we will be subject to the applicable provisions of the Sarbanes-Oxley Act of 2022, as amended. If we are unable to satisfy the requirements of the Sarbanes-Oxley Act

of 2002, as amended, or its internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned.

As a company that intends to list securities in the United States, upon listing of our Common Shares onto Nasdaq, we will be subject to certain of the requirements of the Sarbanes-Oxley Act of 2002, as amended ("**SOX**"). Section 404 of SOX ("**Section 404**") requires companies subject to the reporting requirements of the U.S. securities laws to complete a comprehensive evaluation of its internal controls over financial reporting. To comply with this statute, we will be required to document and test our internal control procedures and our management will be required to assess and issue a report concerning the Company's internal controls over financial reporting. Pursuant to the Jumpstart Our Business Startups Act of 2012 (the "**JOBS Act**"), we would be classified as an "emerging growth company" and be exempt from certain reporting requirements, including the independent auditor attestation requirements of Section 404(b) of SOX. Under this exemption, our independent auditor will not be required to attest to and report on management's assessment of our internal controls over financial reporting during a five-year transition period. We will need to prepare for compliance with Section 404 by strengthening, assessing and testing our system of internal controls to provide the basis for the report. However, the continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming. Furthermore, we believe that our business will grow both domestically and internationally, in which case our internal controls will become more complex and will require significantly more resources and attention to ensure our internal controls remain effective overall. During the course of our testing, management may identify material weaknesses or significant deficiencies, which may not be remedied in a timely manner to meet the deadline imposed by SOX. If management cannot favorably assess the effectiveness of our internal controls over financial reporting, or our independent registered public accounting firm identifies material weaknesses in our internal controls, investor confidence in our financial results may weaken, and the market price of our securities may suffer.

Our Common Shares do not currently trade on a stock exchange in the United States and we do not know whether a market for our Common Shares will develop to provide you with adequate liquidity.

The Common Shares are currently listed only on the TSXV. The Company has applied to list the Common Shares on Nasdaq under the symbol "NGEN". The ability to successfully list our Common Shares onto Nasdaq is uncertain. However, if an active trading market does not develop in the United States, you may have difficulty selling any of the Common Shares that you buy over a U.S. exchange. The Company cannot predict the extent to which investor interest in the Company will lead to the development of an active trading market on the Nasdaq or otherwise, or how liquid that market might become. Listing of our Common Shares on the Nasdaq in addition to the TSXV may increase price volatility on the TSXV and also result in volatility of the trading price on the Nasdaq because trading will be in two markets, which may result in less liquidity on both exchanges. In addition, different liquidity levels, volumes of trading, currencies and market conditions on the two exchanges may result in different prevailing trading prices.

We do not intend to pay dividends on our Common Shares in the foreseeable future, so any returns will be limited to the value of our Common Shares.

We have never declared or paid any cash dividends on our Common Shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to shareholders will therefore be limited to any appreciation in the value of their shares.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Shares, the trading price or trading volume of our Common Shares could decline.

The trading market for our Common Shares will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more securities analysts initiate research with an unfavorable rating or downgrade our Common Shares, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our Common Shares price would likely decline. If few securities analysts commence coverage of us, or if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets

and demand for our securities could decrease, which in turn could cause the price and trading volume of our Common Shares to decline.

We have broad discretion in the use of the net proceeds from any offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from any offering, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from any offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these proceeds effectively could adversely affect our business, financial condition and results of operations. Pending their use, we may invest our net proceeds in a manner that does not produce income or that loses value. Our investments may not yield a favorable return to our investors and may negatively impact the price of our Common Shares.

Investing in our securities is speculative, and investors could lose their entire investment.

An investment in our securities is speculative and may result in the loss of an investor's entire investment. Only potential investors who are experienced in high-risk investments and who can afford to lose their entire investment should consider an investment in our securities.

Our constating documents permit us to issue an unlimited number of Common Shares without additional shareholder approval which could result in dilution.

Our notice of articles and articles permit us to issue an unlimited number of Common Shares. We anticipate that we will, from time to time, issue additional Common Shares in the future. Subject to the requirements of the TSX Venture Exchange, we will not be required to obtain the approval of shareholders for the issuance of additional Common Shares. Any further issuances of Common Shares will result in immediate dilution to existing shareholders and may have an adverse effect on the value of their shareholdings.

The exercise of stock options and warrants could cause dilution.

The exercise of stock options, outstanding warrants and the subsequent resale of such Common Shares in the public market, could adversely affect the prevailing market price of the Common Shares and our ability to raise equity capital in the future at a time and price which it deems appropriate. We may also enter into commitments in the future which would require the issuance of additional Common Shares and we expect to grant additional stock options. Any Common Share issuances from treasury will result in immediate dilution to existing shareholders.

It is possible that our status with regards to whether we are a "passive foreign investment company" may change, which could have adverse U.S. federal income tax consequences for U.S. shareholders.

U.S. investors should be aware that we believe we will not be classified as a passive foreign investment company, or PFIC, during the tax year ended December 31, 2024, however based on current business plans and financial expectations, we expect that we could be a PFIC in future tax years. If we are a PFIC for any year during a U.S. shareholder's holding period of the Common Shares, then such U.S. shareholder will generally be required to treat any gain realized upon a disposition of the Common Shares, or any so-called "excess distribution" received on the Common Shares, as ordinary income, and to pay an interest charge on a portion of such gain or distributions, unless the shareholder makes a timely and effective "qualified electing fund" election, QEF Election, or a "mark-to-market" election with respect to the Common Shares. A U.S. shareholder who makes a QEF Election generally must report on a current basis its share of the Company's net capital gain and ordinary earnings for any year in which the Company is a PFIC, whether or not the Company distributes any amounts to its shareholders. A U.S. shareholder who makes the mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the Common Shares over the shareholder's adjusted tax basis therein. Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of the Common Shares.

It may be difficult for non-Canadian investors to obtain and enforce judgments against us because of our Canadian incorporation and presence.

We are a corporation existing under the laws of the Province of British Columbia, Canada. Several of our directors and officers, and several of the experts are residents of Canada, and all or a substantial portion of their assets, and a substantial portion of the Company's assets, are located outside the U.S. Consequently, although we have appointed an agent for service of process in the U.S., it may be difficult for holders of our securities who reside in the U.S. to effect service within the U.S. upon those directors and officers, and the experts who are not residents of the U.S. It may also be difficult for holders of our securities who reside in the U.S. to realize in the U.S. upon judgments of courts of the U.S. predicated upon our civil liability and the civil liability of our directors, officers and experts under the U.S. federal securities laws. Investors should not assume that Canadian courts would (i) enforce judgments of U.S. courts obtained in actions against the Company or such directors, officers or experts predicated upon the civil liability provisions of the U.S. federal securities laws or the securities or "blue sky" laws of any state or jurisdiction of the U.S. or (ii) enforce, in original actions, liabilities against us or such directors, officers or experts predicated upon the U.S. federal securities laws or any securities or "blue sky" laws of any state or jurisdiction of the U.S.. In addition, the protections afforded by Canadian securities laws may not be available to investors in the U.S.

Upon effectiveness of a registration statement on Form F-10, we will become subject to the informational requirements of the Exchange Act; however, as a foreign private issuer, we would be subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to our U.S. shareholders.

Upon effectiveness of a registration statement on Form F-10, we will become subject to the informational requirements of the Exchange Act; however, we would be a foreign private issuer under applicable U.S. federal securities laws and, therefore, we would not be required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act, as amended, and related rules and regulations, should we become subject to such requirements in the future. As a result, we would not file the same reports that a U.S. domestic issuer would file with the SEC, although we would be required to file with or furnish to the SEC the continuous disclosure documents that we are required to file in Canada under Canadian securities laws. In addition, our officers, directors and principal shareholders would be exempt from the reporting and "short swing" profit recovery provisions of Section 16 of the Exchange Act. Therefore, our shareholders may not know on as timely a basis when our officers, directors and principal shareholders purchase or sell Common Shares as the reporting periods under the corresponding Canadian insider reporting requirements are longer. In addition, as a foreign private issuer, we would be exempt from the proxy rules under the Exchange Act.

We have devoted, and will continue to devote significant resources to regulatory compliance as a public entity. These resource requirements will increase if we successfully list our Common Shares onto Nasdaq.

As a public company, we incur significant legal, accounting and other expenses. Legal, accounting and other expenses associated with public company reporting requirements have increased significantly in recent years. We anticipate that costs may continue to increase with corporate governance related requirements, including, without limitation, requirements under National Instrument 52-109 - Certification of Disclosure in Issuers' Annual and Interim Filings, National Instrument 52-110 - Audit Committees, National Instrument 58-101 - Disclosure of Corporate Governance Practices, the Exchange Act, the Sarbanes-Oxley Act (2002), as amended, as well as rules adopted, and to be adopted, by the SEC, the Nasdaq and the TSX-V.

Our management and other personnel have devoted, and will continue to devote, a substantial amount of time to regulatory compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Our testing, or any subsequent testing by its independent auditor, may in the future reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. We will incur substantial accounting expense and expend significant management efforts to comply with internal control over financial reporting requirements. Moreover, if we are not able to comply with these requirements in a timely manner or if it or its independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our Common Shares could decline, and we could be subject to sanctions or

investigations by applicable securities regulatory authorities, which would require additional financial and management resources.

There is currently no market through which our securities, other than our Common Shares, may be sold.

There is currently no market through which our securities, other than our Common Shares, may be sold and, unless otherwise specified in the applicable prospectus supplement, our Debt Securities, Subscription Receipts, Units or Warrants will not be listed on any securities or stock exchange or any automated dealer quotation system. As a consequence, purchasers may not be able to resell Debt Securities, Subscription Receipts, Units or Warrants purchased under this prospectus. This may affect the pricing of our securities, other than our Common Shares, in the secondary market, the transparency and availability of trading prices, the liquidity of these securities and the extent of issuer regulation. There can be no assurance that an active trading market for our securities, other than our Common Shares, will develop or, if developed, that any such market, including for our Common Shares, will be sustained.

The Debt Securities will be unsecured and will rank equally in right of payment with all of our future unsecured debt.

Unless otherwise indicated in the applicable prospectus supplement, the Debt Securities will be unsecured and will rank equally in right of payment with all of our other existing and future unsecured debt. The Debt Securities will be effectively subordinated to all of our existing and future secured debt to the extent of the assets securing such debt. If we are involved in any bankruptcy, dissolution, liquidation or reorganization, the secured debt holders would, to the extent of the value of the assets securing the secured debt, be paid before the holders of unsecured Debt Securities, including the Debt Securities. In that event, a holder of Debt Securities may not be able to recover any principal or interest due to it under the Debt Securities. See "*Debt Securities*".

General Risks

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA, Health Canada or other regulatory authority investigation of the safety and effectiveness of our product candidates, our manufacturing processes and facilities or our marketing programs. FDA, EMA, Health Canada or other regulatory authority investigations could potentially lead to a recall of our product candidates or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, contract research organizations, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.

We, our collaborators, our CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third

parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U.S., Canadian and international privacy, data protection and other laws, and subject us to litigation and governmental investigations and proceedings by federal, state, provincial and local regulatory entities in the United States and Canada and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that maybe imposed; and could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our Common Shares may be volatile and, in the past, companies that have experienced volatility in the market price of their share have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years and we may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

USE OF PROCEEDS

Unless we otherwise indicate in a prospectus supplement, we currently intend to use the net proceeds from the sale of our securities for general corporate purposes, including funding research and development, intellectual property development, preclinical and clinical expenses, and corporate costs.

By the nature of our business as a clinical stage pharmaceutical company, we had negative operating cash flow for our most recent interim financial period and financial year. To the extent we have negative cash flows in future periods, we may use a portion of our general working capital to fund such negative cash flow. See *"Risk Factors"*.

More detailed information regarding the use of proceeds from the sale of securities, including any determinable milestones at the applicable time, will be described in any applicable prospectus supplement. We may also, from time to time, issue securities otherwise than pursuant to a prospectus supplement to this prospectus.

EARNINGS COVERAGE

If we offer Debt Securities having a term to maturity in excess of one year under this prospectus and any applicable prospectus supplement, the applicable prospectus supplement will include earnings coverage ratios giving effect to the issuance of such securities. See *"Debt Securities"*.

CONSOLIDATED CAPITALIZATION

Except as disclosed below, there have been no material changes in our consolidated share or debt capital since September 30, 2025, the date of our financial statements for the most recently completed financial period. The following table sets forth the consolidated capitalization of the Company as at September 30, 2025, before and after giving effect to the Private Placement, exercises of Warrants, exercises and forfeitures of stock options, and the

amendment of Warrants issued as part of the private placement completed on July 13, 2022 ("2022 Warrants"). This table is illustrative only and should be read in conjunction with the Interim Financial Statements and the Interim MD&A, each of which are incorporated by reference into this Prospectus.

Description	**As at September 30, 2025 before giving effect to the Private Placement, Warrant Exercises, and Option Exercises and Forfeitures**	**Pro Forma as at September 30, 2025 after giving effect to the Private Placement, Warrant Exercises, Option Exercises and Forfeitures, and Amendment of 2022 Warrants**
Assets		
Cash and cash equivalents[(1)]	$11,364,055	$27,287,942
Liabilities		
Current Liabilities[(1)(4)]	$16,019,155	$11,749,736
Equity		
Shareholders Equity[(1)(2)(3)(4)]	$(2,941,703)	$17,251,603
Common Shares[(1)(2)(3)]	73,407,793	79,212,514
Warrants[(1)(2)(3)]	9,030,147	11,263,429
Options[(3)]	11,074,397	9,775,900
Retention Securities	491,667	491,667
Broker Warrants	138,162	138,162

(1) On November 19, 2025, the Company issued 4,785,674 Common Shares and 2,392,832 Warrants pursuant to the Private Placement. The Warrants have an exercise price denominated in a currency that differes from the Company's functional currency, and are therefore treated as a derivative measured at fair value with subsequent changes in fair value accounted for through the statement of loss and comprehensive loss. The fair value of the warrant derivative is recognized on the condensed consolidated interim statements of financial position as a current liability and is based on level 2 inputs (significant observable inputs) as these warrants have not been listed on an exchange and therefore do not trade on an active market. The Company used the Black-Scholes valuation model to estimate fair value as of the closing date of the Private Placement.

(2) During the period of September 30, 2025 through December 12, 2025, the Company issued 159,550 Common Shares pursuant to various exercises of Warrants.

(3) During the period of September 30, 2025 through December 12, 2025, the Company issued 859,497 Common Shares pursuant to exercises of stock options and 439,000 stock options were forfeited.

(4) Pursuant to the private placement completed on July 13, 2022, the Company issued 10,150,000 units of the Company. Each unit issued in the private placement consisted of one Common Share and one-half of one 2022 Warrant. Each 2022 Warrant was originally exercisable for one Common Share at a price of U.S.$1.75 per Common Share until July 13, 2027. On December 12, 2025, the Company amended the exercise price of the 2022 Warrants ("**Amended 2022 Warrants**") to reflect an equivalent price denominated in the Company's functional currency (CA$2.44) at a recent foreign exchange rate thereby derecognizing the warrant deriviative liability associated with the 2022 Warrants upon amendment. The Amended 2022 Warrants are accounted for within Shareholders Equity in the period in which they are amended.

Any applicable prospectus supplement will describe any material change, and the effect of such material change, on the Company's consolidated share or debt capital.

OUTSTANDING SECURITY DATA

As of December 12, 2025, the following securities of the Company were outstanding:

Security	Amount
Common Shares	79,212,514
Warrants to purchase	11,263,429 Common Shares
Options to purchase	9,775,900 Common Shares
Retention Securities to purchase	491,667 Common Shares
Broker Warrants to purchase	138,162 Common Shares

PRIOR SALES

Information in respect of our Common Shares and securities exchangeable for or exercisable into Common Shares issued within the previous twelve month period, as well as in respect of Common Shares that we issued upon the exercise of options granted under our equity incentive plans, and in respect of such equity securities exercisable or convertible into Common Shares that we granted under such equity incentive plans, will be provided as required in a prospectus supplement with respect to the issuance of securities pursuant to such prospectus supplement.

MARKET FOR SECURITIES

The Company's Common Shares are listed and posted for trading on the TSX-V under the symbol "NGEN" and OTCQB under the symbol "NGEN-F". Upon listing of the Common Shares on Nasdaq, the Common Shares will cease trading on the OTCQB. Trading price and volume of the Company's securities will be provided as required for all of our Common Shares in each prospectus supplement to this prospectus.

DESCRIPTION OF THE SECURITIES BEING DISTRIBUTED

Common Shares

The authorized share capital of the Company consists of an unlimited number of Common Shares. As of December 12, 2025, the last trading date before the date of this Prospectus, the Company has an aggregate of 79,212,514 fully paid Common Shares issued and outstanding.

The holders of the Common Shares are entitled to:

- vote at all meetings of shareholders of the Company, except meetings at which only holders of a specified class of shares (of which there is none as at the date of this Prospectus) are entitled to vote;
- receive, subject to the rights, privileges, restrictions and conditions attaching to any other class of shares of the Company (of which there is none as at the date of this Prospectus), any dividends declared by the Company; and
- receive, subject to the rights, privileges, restrictions and conditions attaching to any other class of shares of the Company (of which there is none in existence as at the date of this Prospectus), the remaining property of the Company upon the liquidation, dissolution or winding- up of the Company, whether voluntary or involuntary.

The Common Shares do not have nor are they subject to:

- any pre-emptive, conversion or exchange rights;

- any redemption, retraction, purchase for cancellation or surrender provisions but the Company, if authorized by a resolution of the Board, may purchase, redeem or otherwise acquire any of the Common shares at the price and upon the terms specified in such resolution;

- sinking or purchase fund provisions;

- provisions permitting or restricting the issuance of additional securities and any other material restrictions; or

- provisions requiring a securityholder to contribute additional capital.

The Company's board of directors (the "**Board**"), by a resolution passed by a majority of the votes cast, may:

- establish a maximum number of Common Shares that the Company is authorized to issue;

- increase, reduce or eliminate the maximum number of Common Shares if a maximum has been established;

- change all or any of the unissued Common Shares (which do not have a par value) into shares with par value;

- subdivide or consolidate all or any of its unissued, or fully paid issued, Common Shares into a greater or lesser number of Common Shares, respectively; and

- alter the identifying name of the Common Shares.

The Company's shareholders, by a resolution passed by a two thirds majority of the votes cast, may:

- create special rights or restrictions for, and attach those special rights or restrictions to, the Common Shares;

- vary or delete any special rights or restrictions attached to the Common Shares; and

- otherwise alter the Common Shares or the Company's share structure as permitted under the *Business Corporations Act* (British Columbia).

Debt Securities

The following description of the terms of Debt Securities sets forth certain general terms and provisions of Debt Securities in respect of which a prospectus supplement may be filed. The particular terms and provisions of Debt Securities offered by any prospectus supplement, and the extent to which the general terms and provisions described below may apply thereto, will be described in the prospectus supplement filed in respect of such Debt Securities. Prospective investors should rely on information in the applicable prospectus supplement if it is different from the following information.

Debt Securities may be offered separately or in combination with one or more other securities of the Company. We may, from time to time, issue Debt Securities and incur additional indebtedness other than through the issue of Debt Securities pursuant to this prospectus.

The Debt Securities will be issued under one or more indentures (each, a "**Trust Indenture**"), in each case between the Company and a financial institution or trust company organized under the laws of Canada or any province thereof and authorized to carry on business as a trustee (each, a "**Trustee**"). Such indenture will be subject to and governed by the United States *Trust Indenture Act* of 1939, as amended.

The following description sets forth certain general terms and provisions of the Debt Securities and is not intended to be complete. The particular terms and provisions of the Debt Securities and a description of how the general terms and provisions described below may apply to the Debt Securities will be included in the applicable prospectus

supplement. The following description is subject to the detailed provisions of the applicable Trust Indenture. Accordingly, reference should also be made to the applicable Trust Indenture, a copy of which will be filed by the Company with the securities commissions or similar regulatory authorities in applicable Canadian offering jurisdictions, after it has been entered into, and will be available electronically at www.sedarplus.ca and www.sec.gov/edgar.

General

The applicable Trust Indenture will not limit the aggregate principal amount of Debt Securities that may be issued under such Trust Indenture and will not limit the amount of other indebtedness that we may incur. The applicable Trust Indenture will provide that we may issue Debt Securities from time to time in one or more series and may be denominated and payable in U.S. dollars, Canadian dollars or any foreign currency. Unless otherwise indicated in the applicable prospectus supplement, the Debt Securities will be unsecured obligations of the Company.

We may specify a maximum aggregate principal amount for the Debt Securities of any series and, unless otherwise provided in the applicable prospectus supplement, a series of Debt Securities may be reopened for issuance of additional Debt Securities of such series. The applicable Trust Indenture will also permit the Company to increase the principal amount of any series of the Debt Securities previously issued and to issue that increased principal amount.

Any prospectus supplement for Debt Securities supplementing this prospectus will contain the specific terms and other information with respect to the Debt Securities being offered thereby, including, but not limited to, the following:

- the designation, aggregate principal amount and authorized denominations of such Debt Securities;
- the percentage of principal amount at which the Debt Securities will be issued;
- whether payment on the Debt Securities will be senior or subordinated to other liabilities or obligations of the Company;
- whether the payment of the Debt Securities will be guaranteed by any other person;
- the date or dates, or the methods by which such dates will be determined or extended, on which the Company may issue the Debt Securities and the date or dates, or the methods by which such dates will be determined or extended, on which the Company will pay the principal and any premium on the Debt Securities and the portion (if less than the principal amount) of Debt Securities to be payable upon a declaration of acceleration of maturity;
- whether the Debt Securities will bear interest, the interest rate (whether fixed or variable) or the method of determining the interest rate, the date from which interest will accrue, the dates on which we will pay interest and the record dates for interest payments, or the methods by which such dates will be determined or extended;
- the place or places we will pay principal, premium, if any, and interest, if any, and the place or places where Debt Securities can be presented for registration of transfer or exchange;
- whether and under what circumstances we will be required to pay any additional amounts for withholding or deduction for Canadian taxes with respect to the Debt Securities, and whether and on what terms we will have the option to redeem the Debt Securities rather than pay the additional amounts;
- whether we will be obligated to redeem or repurchase the Debt Securities pursuant to any sinking or purchase fund or other provisions, or at the option of a holder, and the terms and conditions of such redemption;
- whether we may redeem the Debt Securities at its option and the terms and conditions of any such redemption;
- the denominations in which we will issue any registered and unregistered Debt Securities;

- the currency or currency Units for which Debt Securities may be purchased and the currency or currency Units in which the principal and any interest is payable (in either case, if other than Canadian dollars) or if payments on the Debt Securities will be made by delivery of Common Shares or other property;

- whether payments on the Debt Securities will be payable with reference to any index or formula;

- if applicable, our ability to satisfy all or a portion of any redemption of the Debt Securities, any payment of any interest on such Debt Securities or any repayment of the principal owing upon the maturity of such Debt Securities through the issuance of securities of the Company or of any other entity, and any restriction(s) on the persons to whom such securities may be issued;

- whether the Debt Securities will be issued as global securities (defined below) and, if so, the identity of the depositary for the global securities;

- whether the Debt Securities will be issued as unregistered securities (with or without coupons), registered securities or both;

- the periods within which and the terms and conditions, if any, upon which we may redeem the Debt Securities prior to maturity and the price or prices of which, and the currency or currency Units in which, the Debt Securities are payable;

- any events of default or covenants applicable to the Debt Securities;

- any terms under which Debt Securities may be defeased, whether at or prior to maturity;

- whether the holders of any series of Debt Securities have special rights if specified events occur;

- any mandatory or optional redemption or sinking fund or analogous provisions;

- the terms, if any, for any conversion or exchange of the Debt Securities for any other securities;

- rights, if any, on a change of control;

- provisions as to modification, amendment or variation of any rights or terms attaching to the Debt Securities;

- the Trustee under the Trust Indenture pursuant to which the Debt Securities are to be issued;

- whether we will undertake to list the Debt Securities of the series on any securities exchange or automated interdealer quotation system; and

- any other terms, conditions, rights and preferences (or limitations on such rights and preferences) including covenants and events of default which apply solely to a particular series of the Debt Securities being offered which do not apply generally to other Debt Securities, or any covenants or events of default generally applicable to the Debt Securities which do not apply to a particular series of the Debt Securities.

We reserve the right to include in a prospectus supplement specific terms pertaining to the Debt Securities which are not within the options and parameters set forth in this prospectus. In addition, to the extent that any particular terms of the Debt Securities described in a prospectus supplement differ from any of the terms described in this prospectus, the description of such terms set forth in this prospectus shall be deemed to have been superseded by the description of such differing terms set forth in such prospectus supplement with respect to such Debt Securities.

Unless stated otherwise in the applicable prospectus supplement, no holder of Debt Securities will have the right to require the Company to repurchase the Debt Securities and there will be no increase in the interest rate if we become involved in a highly leveraged transaction or have a change of control.

We may issue Debt Securities bearing no interest or interest at a rate below the prevailing market rate at the time of issuance, and offer and sell these securities at a discount below their stated principal amount. We may also sell any of the Debt Securities for a foreign currency or currency unit, and payments on the Debt Securities may be payable in a foreign currency or currency unit. In any of these cases, we will describe certain Canadian federal and U.S. federal income tax consequences and other special considerations in the applicable prospectus supplement.

Unless otherwise indicated in the applicable prospectus supplement, we may issue Debt Securities with terms different from those of Debt Securities previously issued and, without the consent of the holders thereof, reopen a previous issue of a series of Debt Securities and issue additional Debt Securities of such series.

Ranking and Other Indebtedness

Unless otherwise indicated in an applicable prospectus supplement, the Debt Securities will be direct unsecured obligations of the Company. The Debt Securities will be senior or subordinated indebtedness of the Company as described in the applicable prospectus supplement. If the Debt Securities are senior indebtedness, they will rank equally and rateably with all other unsecured indebtedness of the Company from time to time issued and outstanding which is not subordinated. If the Debt Securities are subordinated indebtedness, they will be subordinated to senior indebtedness of the Company as described in the applicable prospectus supplement, and they will rank equally and rateably with other subordinated indebtedness of the Company from time to time issued and outstanding as described in the applicable prospectus supplement. We reserve the right to specify in a prospectus supplement whether a particular series of subordinated Debt Securities is subordinated to any other series of subordinated Debt Securities.

The Board may establish the extent and manner, if any, to which payment on or in respect of a series of Debt Securities will be senior or will be subordinated to the prior payment of our other liabilities and obligations and whether the payment of principal, premium, if any, and interest, if any, will be guaranteed by any other person and the nature and priority of any security.

Registration of Debt Securities

Debt Securities in Book Entry Form

Unless otherwise indicated in an applicable prospectus supplement, Debt Securities of any series may be issued in whole or in part in the form of one or more global securities ("**Global Securities**") registered in the name of a designated clearing agency (a "**Depositary**") or its nominee and held by or on behalf of the Depositary in accordance with the terms of the applicable Trust Indenture. The specific terms of the depositary arrangement with respect to any portion of a series of Debt Securities to be represented by a Global Security will, to the extent not described herein, be described in the prospectus supplement relating to such series. We anticipate that the provisions described in this section will apply to all depositary arrangements.

Upon the issuance of a Global Security, the Depositary or its nominee will credit, in its book-entry and registration system, the respective principal amounts of the Debt Securities represented by the Global Security to the accounts of such participants that have accounts with the Depositary or its nominee ("**Participants**"). Such accounts are typically designated by the underwriters, dealers or agents participating in the distribution of the Debt Securities or by the Company if such Debt Securities are offered and sold directly by the Company. Ownership of beneficial interests in a Global Security will be limited to Participants or persons that may hold beneficial interests through Participants. With respect to the interests of Participants, ownership of beneficial interests in a Global Security will be shown on, and the transfer of that ownership will be effected only through records maintained by the Depositary or its nominee. With respect to the interests of persons other than Participants, ownership of beneficial interests in a Global Security will be shown on, and the transfer of that ownership will be effected only through records maintained by Participants or persons that hold through Participants. The laws of some states in the United States may require that certain purchasers of securities take physical delivery of such securities in definitive form.

So long as the Depositary for a Global Security, or its nominee, is the registered owner of such Global Security, such Depositary or such nominee, as the case may be, will be considered the sole owner or holder of the Debt Securities represented by such Global Security for all purposes under the applicable Trust Indenture and payments of principal,

premium, if any, and interest, if any, on the Debt Securities represented by a Global Security will be made by the Company to the Depositary or its nominee. We expect that the Depositary or its nominee, upon receipt of any payment of principal, premium, if any, or interest, if any, will credit Participants' accounts with payments in amounts proportionate to their respective beneficial interests in the principal amount of the Global Security as shown on the records of such Depositary or its nominee. We also expect that payments by Participants to owners of beneficial interests in a Global Security held through such Participants will be governed by standing instructions and customary practices and will be the responsibility of such Participants.

Conveyance of notices and other communications by the Depositary to direct Participants, by direct Participants to indirect Participants and by direct and indirect Participants to beneficial owners will be governed by arrangements among them, subject to any statutory or regulatory requirements as may be in effect from time to time. Beneficial owners of Debt Securities may wish to take certain steps to augment transmission to them of notices of significant events with respect to the Debt Securities, such as redemptions, tenders, defaults and proposed amendments to the Trust Indenture.

Owners of beneficial interests in a Global Security will not be entitled to have the Debt Securities represented by such Global Security registered in their names, will not receive or be entitled to receive physical delivery of such Debt Securities in certificated non-book-entry form, and will not be considered the owners or holders thereof under the applicable Trust Indenture, and the ability of a holder to pledge a debt security or otherwise take action with respect to such holder's interest in a debt security (other than through a Participant) may be limited due to the lack of a physical certificate.

No Global Security may be exchanged in whole or in part for Debt Securities registered, and no transfer of a Global Security in whole or in part may be registered, in the name of any person other than the Depositary for such Global Security or any nominee of such Depositary unless: (i) the Depositary is no longer willing or able to discharge properly its responsibilities as depositary and the Company is unable to locate a qualified successor; (ii) the Company at its option elects, or is required by law, to terminate the book-entry system through the Depositary or the book-entry system ceases to exist; or (iii) if provided for in the Trust Indenture, after the occurrence of an event of default thereunder (provided the Trustee has not waived the event of default in accordance with the terms of the Trust Indenture), Participants acting on behalf of beneficial holders representing, in aggregate, a threshold percentage of the aggregate principal amount of the Debt Securities then outstanding advise the Depositary in writing that the continuation of a book-entry system through the Depositary is no longer in their best interest.

If one of the foregoing events occurs, such Global Security shall be exchanged for certificated non-book-entry Debt Securities of the same series in an aggregate principal amount equal to the principal amount of such Global Security and registered in such names and denominations as the Depositary may direct.

The Company, any underwriters, dealers or agents and any Trustee identified in an accompanying prospectus supplement, as applicable, will not have any liability or responsibility for (i) records maintained by the Depositary relating to beneficial ownership interests in the Debt Securities held by the Depositary or the book-entry accounts maintained by the Depositary, (ii) maintaining, supervising or reviewing any records relating to any such beneficial ownership interests, or (iii) any advice or representation made by or with respect to the Depositary and contained in this prospectus or in any prospectus supplement or Trust Indenture with respect to the rules and regulations of the Depositary or at the direction of Depositary Participants.

Unless otherwise stated in the applicable prospectus supplement, CDS Clearing and Depository Services Inc. or its successor will act as Depositary for any Debt Securities represented by a Global Security.

Debt Securities in Certificated Form

A series of the Debt Securities may be issued in definitive form, solely as registered securities, solely as unregistered securities or as both registered securities and unregistered securities. Unless otherwise indicated in the applicable prospectus supplement, unregistered securities will have interest coupons attached.

In the event that the Debt Securities are issued in certificated non-book-entry form, and unless otherwise indicated in the applicable prospectus supplement, payment of principal, premium, if any, and interest, if any, on the Debt Securities (other than a Global Security) will be made at the office or agency of the Trustee or, at the option of the Company, by the Company by way of cheque mailed or delivered to the address of the person entitled at the address appearing in the security register of the Trustee or electronic funds wire or other transmission to an account of the person entitled to receive such payments. Unless otherwise indicated in the applicable prospectus supplement, payment of interest, if any, will be made to the persons in whose name the Debt Securities are registered at the close of business on the day or days specified by the Company.

At the option of the holder of Debt Securities, registered securities of any series will be exchangeable for other registered securities of the same series, of any authorized denomination and of a like aggregate principal amount and tenor. If, but only if, provided in an applicable prospectus supplement, unregistered securities (with all unmatured coupons, except as provided below, and all matured coupons in default) of any series may be exchanged for registered securities of the same series, of any authorized denominations and of a like aggregate principal amount and tenor. In such event, unregistered securities surrendered in a permitted exchange for registered securities between a regular record date or a special record date and the relevant date for payment of interest shall be surrendered without the coupon relating to such date for payment of interest, and interest will not be payable on such date for payment of interest in respect of the registered security issued in exchange for such unregistered security, but will be payable only to the holder of such coupon when due in accordance with the terms of the Trust Indenture. Unless otherwise specified in an applicable prospectus supplement, unregistered securities will not be issued in exchange for registered securities.

The applicable prospectus supplement may indicate the places to register a transfer of the Debt Securities in definitive form. Except for certain restrictions to be set forth in the Trust Indenture, no service charge will be payable by the holder for any registration of transfer or exchange of the Debt Securities in definitive form, but we may, in certain instances, require a sum sufficient to cover any tax or other governmental charges payable in connection with these transactions.

Warrants

General

This section describes the general terms that will apply to any Warrants for the purchase of Common Shares, or equity Warrants, or for the purchase of Debt Securities, or debt Warrants.

Warrants may be issued independently or together with other securities, and Warrants sold with other securities may be attached to or separate from the other securities. Warrants will be issued under one or more warrant agency agreements to be entered into by the Company and with one or more financial institutions or trust companies acting as warrant agent.

We will deliver an undertaking to the securities regulatory authority in each of the provinces and territories of Canada that we will not distribute Warrants that, according to the aforementioned terms as described in the applicable prospectus supplement for Warrants supplementing this prospectus, are “novel” specified derivatives within the meaning of Canadian securities legislation, separately to any member of the public in Canada, unless such prospectus supplement containing the specific terms of the Warrants to be distributed separately is first approved by or on behalf of the securities commissions or similar regulatory authorities in each of the provinces and territories of Canada where the Warrants will be distributed.

This summary of some of the provisions of the Warrants is not complete. The statements made in this prospectus relating to any warrant agreement and Warrants to be issued under this prospectus are summaries of certain anticipated provisions thereof and do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all provisions of the applicable warrant agreement. You should refer to the warrant indenture or warrant agency agreement relating to the specific Warrants being offered for the complete terms of the Warrants. A copy of any warrant indenture or warrant agency agreement relating to an offering or Warrants will be filed by the Company with the securities commissions or similar regulatory authorities in applicable Canadian offering jurisdictions and the United States, after it has been entered into, and will be available electronically on SEDAR+ at www.sedarplus.ca and EDGAR at www.sec.gov/edgar.

The applicable prospectus supplement relating to any Warrants that we offer will describe the particular terms of those Warrants and include specific terms relating to the offering.

Original purchasers of Warrants (if offered separately) will have a contractual right of rescission against the Company in respect of the exercise of such warrant. The contractual right of rescission will entitle such original purchasers to receive, upon surrender of the underlying securities acquired upon exercise of the warrant, the total of the amount paid on original purchase of the warrant and the amount paid upon exercise, in the event that this prospectus (as supplemented or amended) contains a misrepresentation, provided that: (i) the exercise takes place within 180 days of the date of the purchase of the warrant under the applicable prospectus supplement; and (ii) the right of rescission is exercised within 180 days of the date of purchase of the warrant under the applicable prospectus supplement. This contractual right of rescission will be consistent with the statutory right of rescission described under section 131 of the *Securities Act* (British Columbia), and is in addition to any other right or remedy available to original purchasers under section 131 of the *Securities Act* (British Columbia) or otherwise at law.

In an offering of Warrants, or other convertible securities, original purchasers are cautioned that the statutory right of action for damages for a misrepresentation contained in the prospectus is limited, in certain provincial and territorial securities legislation, to the price at which the Warrants, or other convertible securities, are offered to the public under the prospectus offering. This means that, under the securities legislation of certain provinces and territories, if the purchaser pays additional amounts upon conversion, exchange or exercise of such securities, those amounts may not be recoverable under the statutory right of action for damages that applies in those provinces and territories. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of these rights, or consult with a legal advisor.

Equity Warrants

The particular terms of each issue of equity Warrants will be described in the applicable prospectus supplement. This description will include, where applicable:

- the designation and aggregate number of equity Warrants;
- the price at which the equity Warrants will be offered;
- the currency or currencies in which the equity Warrants will be offered;
- the date on which the right to exercise the equity Warrants will commence and the date on which the right will expire;
- the number of Common Shares that may be purchased upon exercise of each equity warrant and the price at which and currency or currencies in which the Common Shares may be purchased upon exercise of each equity warrant;
- the terms of any provisions allowing or providing for adjustments in (i) the number and/or class of Common Shares that may be purchased, (ii) the exercise price per Common Share or (iii) the expiry of the equity Warrants;
- whether we will issue fractional shares;
- whether we have applied to list the equity Warrants or the underlying shares on a securities exchange or automated interdealer quotation system;
- the designation and terms of any securities with which the equity Warrants will be offered, if any, and the number of the equity Warrants that will be offered with each security;
- the date or dates, if any, on or after which the equity Warrants and the related securities will be transferable separately;

- whether the equity Warrants will be subject to redemption or call and, if so, the terms of such redemption or call provisions;

- material U.S. and Canadian federal income tax consequences of owning the equity Warrants; and

- any other material terms or conditions of the equity Warrants.

Debt Warrants

The particular terms of each issue of debt Warrants will be described in the related prospectus supplement. This description will include, where applicable:

- the designation and aggregate number of debt Warrants;

- the price at which the debt Warrants will be offered;

- the currency or currencies in which the debt Warrants will be offered;

- the designation and terms of any securities with which the debt Warrants are being offered, if any, and the number of the debt Warrants that will be offered with each security;

- the date or dates, if any, on or after which the debt Warrants and the related securities will be transferable separately;

- the principal amount of Debt Securities that may be purchased upon exercise of each debt warrant and the price at which and currency or currencies in which that principal amount of Debt Securities may be purchased upon exercise of each debt warrant;

- the date on which the right to exercise the debt Warrants will commence and the date on which the right will expire;

- the minimum or maximum amount of debt Warrants that may be exercised at any one time;

- whether the debt Warrants will be subject to redemption or call, and, if so, the terms of such redemption or call provisions;

- material U.S. and Canadian federal income tax consequences of owning the debt Warrants; and

- any other material terms or conditions of the debt Warrants.

Prior to the exercise of their Warrants, holders of Warrants will not have any of the rights of holders of the securities subject to the Warrants.

Units

We may issue Units, which may consist of one or more Common Shares, Warrants or any combination of securities as is specified in the relevant prospectus supplement. In addition, the relevant prospectus supplement relating to an offering of Units will describe all material terms of any Units offered, including, as applicable:

- the designation and aggregate number of Units being offered;

- the price at which the Units will be offered;

- the designation, number and terms of the securities comprising the Units and any agreement governing the Units;

- the date or dates, if any, on or after which the securities comprising the Units will be transferable separately;

- whether we will apply to list the Units on a securities exchange or automated interdealer quotation system;

- material U.S. and Canadian federal income tax consequences of owning the Units, including how the purchase price paid for the Units will be allocated among the securities comprising the Units; and

- any other material terms or conditions of the Units.

Subscription Receipts

We may issue Subscription Receipts separately or in combination with one or more other securities. The Subscription Receipts will entitle holders thereof to receive, upon satisfaction of certain release conditions and for no additional consideration, Common Shares, Warrants or any combination thereof. Subscription Receipts will be issued pursuant to one or more subscription receipt agreements (each, a "**Subscription Receipt Agreement**"), each to be entered into between the Company and an escrow agent (the "**Escrow Agent**") that will be named in the relevant prospectus supplement. Each Escrow Agent will be a financial institution organized under the laws of Canada or a province thereof and authorized to carry on business as a trustee. If underwriters or agents are used in the sale of any Subscription Receipts, one or more of such underwriters or agents may also be a party to the Subscription Receipt Agreement governing the Subscription Receipts sold to or through such underwriter or agent.

The following description sets forth certain general terms and provisions of Subscription Receipts that may be issued hereunder and is not intended to be complete. The statements made in this prospectus relating to any Subscription Receipt Agreement and Subscription Receipts to be issued thereunder are summaries of certain anticipated provisions thereof and are subject to, and are qualified in their entirety by reference to, all provisions of the applicable Subscription Receipt Agreement. Prospective investors should refer to the Subscription Receipt Agreement relating to the specific Subscription Receipts being offered for the complete terms of the Subscription Receipts. We will file a copy of any Subscription Receipt Agreement relating to an offering of Subscription Receipts with the securities commissions or similar regulatory authorities in applicable Canadian offering jurisdictions and the United States, after it has been entered into, and such Subscription Receipt Agreement will be available electronically on SEDAR+ at www.sedarplus.ca and EDGAR at www.sec.gov/edgar.

General

The prospectus supplement and the Subscription Receipt Agreement for any Subscription Receipts that we may offer will describe the specific terms of the Subscription Receipts offered. This description may include, but may not be limited to, any of the following, if applicable:

- the designation and aggregate number of Subscription Receipts being offered;

- the price at which the Subscription Receipts will be offered;

- the designation, number and terms of the Common Shares, Warrants or a combination thereof to be received by the holders of Subscription Receipts upon satisfaction of the release conditions, and any procedures that will result in the adjustment of those numbers;

- the conditions (the "**Release Conditions**") that must be met in order for holders of Subscription Receipts to receive, for no additional consideration, the Common Shares, Warrants or a combination thereof;

- the procedures for the issuance and delivery of the Common Shares, Warrants or a combination thereof to holders of Subscription Receipts upon satisfaction of the Release Conditions;

- whether any payments will be made to holders of Subscription Receipts upon delivery of the Common Shares, Warrants or a combination thereof upon satisfaction of the Release Conditions;

- the identity of the Escrow Agent;

- the terms and conditions under which the Escrow Agent will hold all or a portion of the gross proceeds from the sale of Subscription Receipts, together with interest and income earned thereon (collectively, the "**Escrowed Funds**"), pending satisfaction of the Release Conditions;

- the terms and conditions pursuant to which the Escrow Agent will hold Common Shares, Warrants or a combination thereof pending satisfaction of the Release Conditions;

- the terms and conditions under which the Escrow Agent will release all or a portion of the Escrowed Funds to the Company upon satisfaction of the Release Conditions;

- if the Subscription Receipts are sold to or through underwriters or agents, the terms and conditions under which the Escrow Agent will release a portion of the Escrowed Funds to such underwriters or agents in payment of all or a portion of their fees or commissions in connection with the sale of the Subscription Receipts;

- procedures for the refund by the Escrow Agent to holders of Subscription Receipts of all or a portion of the subscription price of their Subscription Receipts, plus any pro rata entitlement to interest earned or income generated on such amount, if the Release Conditions are not satisfied;

- any contractual right of rescission to be granted to initial purchasers of Subscription Receipts in the event that this prospectus, the prospectus supplement under which Subscription Receipts are issued or any amendment hereto or thereto contains a misrepresentation;

- any entitlement of NervGen to purchase the Subscription Receipts in the open market by private agreement or otherwise;

- whether we will issue the Subscription Receipts as global securities and, if so, the identity of the depository for the global securities;

- whether we will issue the Subscription Receipts as bearer securities, as registered securities or both;

- provisions as to modification, amendment or variation of the Subscription Receipt Agreement or any rights or terms of the Subscription Receipts, including upon any subdivision, consolidation, reclassification or other material change of the Common Shares, Warrants or other NervGen securities, any other reorganization, amalgamation, merger or sale of all or substantially all of the Company's assets or any distribution of property or rights to all or substantially all of the holders of Common Shares;

- whether we will apply to list the Subscription Receipts on a securities exchange or automated interdealer quotation system;

- material U.S. and Canadian federal income tax consequences of owning the Subscription Receipts; and

- any other material terms or conditions of the Subscription Receipts.

Original purchasers of Subscription Receipts will have a contractual right of rescission against the Company in respect of the conversion of the subscription receipt. The contractual right of rescission will entitle such original purchasers to receive the amount paid on original purchase of the subscription receipt upon surrender of the underlying securities gained thereby, in the event that this prospectus (as supplemented or amended) contains a misrepresentation, provided that: (i) the conversion takes place within 180 days of the date of the purchase of the subscription receipt under this

prospectus; and (ii) the right of rescission is exercised within 180 days of the date of purchase of the subscription receipt under the applicable prospectus supplement. This contractual right of rescission will be consistent with the statutory right of rescission described under section 131 of the *Securities Act* (British Columbia), and is in addition to any other right or remedy available to original purchasers under section 131 of the *Securities Act* (British Columbia) or otherwise at law.

Rights of Holders of Subscription Receipts Prior to Satisfaction of Release Conditions

The holders of Subscription Receipts will not be, and will not have the rights of, shareholders of NervGen. Holders of Subscription Receipts are entitled only to receive Common Shares, Warrants or a combination thereof on exchange of their Subscription Receipts, plus any cash payments, all as provided for under the Subscription Receipt Agreement and only once the Release Conditions have been satisfied. If the Release Conditions are not satisfied, holders of Subscription Receipts shall be entitled to a refund of all or a portion of the subscription price thereof and all or a portion of the pro rata share of interest earned or income generated thereon, as provided in the Subscription Receipt Agreement.

Escrow

The Subscription Receipt Agreement will provide that the Escrowed Funds will be held in escrow by the Escrow Agent, and such Escrowed Funds will be released to the Company (and, if the Subscription Receipts are sold to or through underwriters or agents, a portion of the Escrowed Funds may be released to such underwriters or agents in payment of all or a portion of their fees in connection with the sale of the Subscription Receipts) at the time and under the terms specified by the Subscription Receipt Agreement. If the Release Conditions are not satisfied, holders of Subscription Receipts will receive a refund of all or a portion of the subscription price for their Subscription Receipts, plus their pro rata entitlement to interest earned or income generated on such amount, if provided for in the Subscription Receipt Agreement, in accordance with the terms of the Subscription Receipt Agreement. Common Shares or Warrants may be held in escrow by the Escrow Agent and will be released to the holders of Subscription Receipts following satisfaction of the Release Conditions at the time and under the terms specified in the Subscription Receipt Agreement.

Modifications

The Subscription Receipt Agreement will specify the terms upon which modifications and alterations to the Subscription Receipts issued thereunder may be made by way of a resolution of holders of Subscription Receipts at a meeting of such holders or consent in writing from such holders. The number of holders of Subscription Receipts required to pass such a resolution or execute such a written consent will be specified in the Subscription Receipt Agreement.

The Subscription Receipt Agreement will also specify that we may amend any Subscription Receipt Agreement and the Subscription Receipts, without the consent of the holders of the Subscription Receipts, to cure any ambiguity, to cure, correct or supplement any defective or inconsistent provision, or in any other manner that will not materially and adversely affect the interests of the holders of outstanding Subscription Receipts or as otherwise specified in the Subscription Receipt Agreement.

The foregoing summary of certain of the principal provisions of the securities is a summary of anticipated terms and conditions only and is qualified in its entirety by the description in the applicable prospectus supplement under which any securities are being offered.

PLAN OF DISTRIBUTION

New Issue

We may sell securities to or through underwriters or dealers, and also may sell securities to one or more other purchasers directly or through agents, including sales pursuant to ordinary brokerage transactions and transactions in which a broker-dealer solicits purchasers or may issue securities in whole or in partial payment of the purchase price

of assets acquired by us or our subsidiaries, or any other method pursuant to applicable law. Each prospectus supplement will set forth the terms of the offering or issue, including the name or names of any underwriters, agents or selling securityholders, the purchase price or prices of the securities, the proceeds to us from the sale of the securities and any commissions, fees, discounts and other items constituting underwriters', dealers' or agents' compensation.

Our securities may be sold, from time to time in one or more transactions at a fixed price or prices which may be changed or at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices, including sales in transactions that are deemed to be ATM Distributions, including sales made directly on the TSX-V or other existing trading markets for the securities. The prices at which the securities may be offered may vary between purchasers and during the period of distribution. If, in connection with the offering of securities at a fixed price or prices, the underwriters have made a *bona fide* effort to sell all of the securities at the initial offering price fixed in the applicable prospectus supplement, the public offering price may be decreased and thereafter further changed, from time to time, to an amount not greater than the initial public offering price fixed in such prospectus supplement, in which case the compensation realized by the underwriters will be decreased by the amount that the aggregate price paid by purchasers for the securities is less than the gross proceeds paid by our underwriters.

Underwriters, dealers and agents who participate in the distribution of the securities may be entitled to, under agreements to be entered into with us, indemnification by us against certain liabilities, including liabilities under the U.S. *Securities Act* and applicable Canadian provincial securities legislation, or to contribution with respect to payments which such underwriters, dealers or agents may be required to make in respect thereof. Such underwriters, dealers and agents may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

No underwriter or dealer involved in an ATM Distribution, no affiliate of such underwriter or dealer and no person acting jointly or in concert with such underwriter or dealer has over-allotted, or will over allot, the Company's securities in connection with an ATM Distribution of the Company's securities or effect any other transactions that are intended to stabilize the market price of the Company's securities during an ATM Distribution.

In connection with any offering of our securities other than in an ATM Distribution, the underwriters may over-allot or effect transactions which stabilize or maintain the market price of our securities offered at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. Each prospectus supplement will set forth the terms of such transactions.

Secondary Offering

This prospectus may also, from time to time, relate to the offering of Common Shares by certain selling securityholders. The prospectus supplement that we will file in connection with any offering of Common Shares by selling securityholders will include the following information:

- the names of the selling securityholders;
- the principal securityholder of the selling securityholder if the selling securityholder is not an individual;
- the number or amount of Common Shares owned, controlled or directed by each selling securityholder;
- the number or amount of Common Shares being distributed for the account of each selling securityholder;
- the number or amount of securities to be owned, controlled or directed by the selling securityholders after the distribution and the percentage that number or amount represents of the total number of our outstanding securities;
- the date or dates the selling securityholder acquired the Common Shares if such Common Shares were acquired within two years preceding the date of this prospectus;

- if the selling securityholder acquired any Common Shares in the 12 months preceding the date of the applicable prospectus supplement, the cost thereof to the securityholder in the aggregate and on an average cost per security basis; and

- whether such Common Shares are owned by the selling securityholders both of record and beneficially, of record only or beneficially only.

The selling securityholders may sell all or a portion of the Common Shares beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If Common Shares are sold through underwriters or broker-dealers, the selling securityholders will be responsible for underwriting discounts or commissions or agent's commissions. Common Shares may be sold by the selling securityholders in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions, as follows:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;

- in the over-the-counter market;

- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;

- through the writing of options, whether such options are listed on an options exchange or otherwise;

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

- an exchange distribution in accordance with the rules of the TSX-V;

- privately negotiated transactions;

- short sales;

- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;

- a combination of any such methods of sale; and

- any other method permitted pursuant to applicable law.

If the selling securityholders effect such transactions by selling the Common Shares to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling securityholders or commissions from purchasers of our Common Shares for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the Common Shares or otherwise, the selling securityholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the Common Shares in the course of hedging in positions they assume. The selling securityholders may also sell the Common Shares short and deliver the Common Shares covered by this prospectus to close out short positions and to return borrowed shares in connection

with such short sales. The selling securityholders may also loan or pledge the Common Shares to broker-dealers that in turn may sell such shares.

CERTAIN INCOME TAX CONSIDERATIONS

The applicable prospectus supplement may describe certain Canadian federal and U.S. federal income tax consequences to an investor who is a non-resident of Canada or to an investor who is a resident of Canada acquiring, owning and disposing of any of our securities offered thereunder. The applicable prospectus supplement may also describe certain U.S. federal income tax consequences of the acquisition, ownership and disposition of any of our securities offered thereunder by an initial investor who is a U.S. person (within the meaning of the U.S. Internal Revenue Code of 1986), including, to the extent applicable, such consequences relating to debt securities payable in a currency other than the U.S. dollar, issued at an original issue discount for U.S. federal income tax purposes or containing early redemption provisions or other special items. Investors should read the tax discussion in any prospectus supplement with respect to a particular offering and consult their own tax advisors with respect to their own particular circumstances.

AGENT FOR SERVICE OF PROCESS

Dr. Randall E. Kaye, Krista L. McKerracher, Dr. Adam H. Rogers and J. Craig Thompson, directors of the Company, reside outside of Canada and have appointed NervGen as agent for service of process. Purchasers are advised that it may not be possible for investors to enforce judgments obtained in Canada against any person or company that is incorporated, continued or otherwise organized under the laws of a foreign jurisdiction or resides outside of Canada, even if the party has appointed an agent for service of process.

Name of Person	Name and Address of Agent
Dr. Randall E. Kaye, Director Krista L. McKerracher, Director J. Craig Thompson, Director Dr. Adam H. Rogers, Director	NervGen Pharma Corp. 112-970 Burrard Street, Unit 1290 Vancouver, British Columbia V6Z 2R4

AUDITORS, TRANSFER AGENT AND REGISTRAR

The auditors of the Company are KPMG LLP, Chartered Professional Accountants through its offices located on the 11th Floor at 777 Dunsmuir Street, Vancouver, British Columbia, Canada V7Y 1K3. KPMG LLP has confirmed that they are independent with respect to the Company within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada and any applicable legislation or regulations, and also that they are independent accountants with respect to the Company under all relevant U.S. professional and regulatory standards.

As of the date of this prospectus, the registrar and transfer agent for the Common Shares is Computershare Investor Services Inc. at its offices in Vancouver, British Columbia.

LEGAL MATTERS

Certain legal matters related to our securities offered by this prospectus will be passed upon on behalf of the Company by Blake, Cassels & Graydon LLP, with respect to matters of Canadian law, and Paul Hastings LLP, with respect to matters of U.S. law. None of Blake, Cassels & Graydon, Paul Hastings LLP, nor any partner, principal or employee thereof, as applicable, received or has received a direct or indirect interest in the Company or of any associate or affiliate of the Company. As at the date hereof, the aforementioned persons and the partners, principals and employees, as applicable, of each of the aforementioned experts, do not beneficially own, directly or indirectly, any securities of the Company.

EXEMPTION FROM NATIONAL INSTRUMENT 44-101

Pursuant to a decision of the Autorité des marchés financiers ("**AMF**") dated October 31, 2024, the Company was granted exemptive relief from the requirement that this prospectus as well as the documents incorporated by reference herein and any applicable prospectus supplement and the documents incorporated by reference therein to be filed in relation to an ATM Distribution be filed with the AMF in the French language. This exemptive relief is granted on the condition that this prospectus, any applicable prospectus supplement and the documents incorporated by reference herein and therein be filed with the AMF in the French language if the Company offers securities to Québec purchasers in connection with an offering other than in relation to an ATM Distribution.

WHERE YOU CAN FIND MORE INFORMATION

We are required to file with the securities commission or authority in each of the provinces and territories of Canada annual and quarterly reports, material change reports and other information. You may read any document we file with or furnish to the securities commissions and authorities of the provinces and territories of Canada through SEDAR+ at www.sedarplus.ca. In addition, upon effectiveness of the registration statement on Form F-10, we will be subject to the informational requirements of the *Exchange Act*, and, in accordance with the *Exchange Act*, we will also file reports with, and furnish other information to, the SEC. Under a multijurisdictional disclosure system adopted by the United States and Canada, these reports and other information (including financial information) may be prepared in accordance with the disclosure requirements of Canada, which differ in certain respects from those in the United States. As a foreign private issuer, we will be exempt from the rules under the *Exchange Act* prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, may not be required to publish financial statements as promptly as U.S. companies.

ENFORCEABILITY OF CIVIL LIABILITIES

We are a company incorporated under the *Business Corporations Act* (British Columbia). Most of our directors and officers are residents of Canada or otherwise reside in the United States, and all or a substantial portion of their assets may be, and a substantial portion of the Company's assets are, located outside the United States. We have appointed an agent for service of process in the United States, but it may be difficult for holders of securities who reside in the United States to effect service within the United States upon those directors, officers and experts who are not residents of the United States. It may also be difficult for holders of securities who reside in the United States to realize in the United States upon judgments of courts of the United States predicated upon our civil liability and the civil liability of our directors, officers and experts under the United States federal securities laws. It is unlikely to be a defence in a Canadian court to the enforcement of a judgment of a U.S. court that the judgment is predicated solely upon civil liability under U.S. federal securities laws or the securities or "blue sky" laws of any state within the United States. There is substantial doubt whether an action could be brought in Canada in the first instance on the basis of the liability predicated solely upon U.S. federal securities laws.

We will file with the SEC, concurrently with our registration statement on Form F-10 of which this prospectus is a part, an appointment of agent for service of process on Form F-X. Under the Form F-X, we will appoint Cogency Global Inc. as our agent for service of process in the United States in connection with any investigation or administrative proceeding conducted by the SEC, and any civil suit or action brought against or involving us in a U.S. court arising out of or related to or concerning the offering of securities under this prospectus.

PURCHASERS' STATUTORY RIGHTS OF WITHDRAWAL AND RESCISSION

Securities legislation in certain of the provinces and territories of Canada provides purchasers with the right to withdraw from an agreement to purchase securities. This right may be exercised within two business days after receipt or deemed receipt of a prospectus or a prospectus supplement relating to the securities purchased by a purchaser and any amendments thereto. In several of the provinces, the securities legislation further provides a purchaser with remedies for rescission or, in some jurisdictions, revision of the price or damages if the prospectus or a prospectus supplement relating to the securities purchased by a purchaser and any amendments thereto contain a misrepresentation or is not delivered to the purchaser, provided that the remedies for recession, revision of the price or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the

purchaser's province. However, purchasers of securities under an ATM Distribution will not have the right to withdraw from an agreement to purchase securities and will not have remedies for rescission or, in some jurisdictions, revisions of the price or damages for non-delivery of the prospectus, because this prospectus, prospectus supplements relating to securities purchased by the purchaser under an ATM Distribution and any amendment relating to securities purchased by the purchaser under an ATM Distribution will not be sent or delivered, as permitted under Part 9 of NI 44-102.

Securities legislation in some provinces and territories of Canada further provides purchasers with remedies for rescission or, in some jurisdictions, revisions of the price or damages if the prospectus, prospectus supplement, and any amendment relating to securities purchased by a purchaser contains a misrepresentation. Those remedies must be exercised by the purchaser within the time limit prescribed by securities legislation. Any remedies under securities legislation that a purchaser of securities under an ATM Distribution may have against the Company or agents for rescission or, in some jurisdictions, revisions of the price or damages if this prospectus, prospectus supplements relating to securities purchased by the purchaser and any amendment relating to securities purchased by the purchaser contain a misrepresentation will remain unaffected by the non-delivery referred to above. A purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of these rights or consult with a legal adviser. Rights and remedies may also be available to purchasers under U.S. law; purchasers may wish to consult with a U.S. lawyer for particulars of these rights.

In an offering of warrants, or other convertible, exchangeable or exercisable securities, original purchasers are cautioned that the statutory right of action for damages under Canadian securities laws for a misrepresentation contained in the prospectus is limited, in certain provincial securities legislation, to the price at which the warrants, or other convertible securities, are offered to the public under the prospectus offering. This means that, under the securities legislation of certain provinces and territories, if the purchaser pays additional amounts upon conversion, exchange or exercise of such securities, those amounts may not be recoverable under the statutory right of action for damages that applies in those provinces or territories. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of these rights or consult with a legal advisor.

CERTIFICATE OF THE COMPANY

Dated: December 15, 2025

This amended and restated short form prospectus, together with the documents incorporated in this amended and restated short form prospectus by reference, constitutes full, true and plain disclosure of all material facts relating to the securities offered by this amended and restated short form prospectus as required by the securities legislation of each of the provinces and territories of Canada.

The Company:

(signed) "Adam Rogers"	*(signed) "William Adams"*
Interim Chief Executive Officer	Chief Financial Officer

On behalf of the Board of Directors

(signed) "John Ruffolo"	*(signed) "Neil Klompas"*
Director	Director